

RULEMAKING ISSUE
(Affirmation)

July 26, 2000

SECY-00-0159

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations /RA/

SUBJECT: FINAL RULE AMENDING THE FITNESS-FOR-DUTY RULE

PURPOSE:

To obtain Commission approval to publish a final rule in the Federal Register to amend the fitness-for-duty (FFD) regulations.

SUMMARY:

The final rule will revise 10 CFR Part 26 to ensure compatibility with changes the Department of Health and Human Services (HHS) has made to its guidelines, make other changes that will reduce unnecessary regulatory burden in some areas, clarify the Commission's original intent of the rule, and improve overall program effectiveness and efficiency. The final rule also grants a December 30, 1993, petition for rulemaking (PRM) submitted by Virginia Power, by changing

CONTACTS:

Garmon West, Jr., NRR
(301) 415-1044
fitnessforduty@nrc.gov

Richard P. Rosano, NRR
(301) 415-2933
fitnessforduty@nrc.gov

the audit frequency of FFD programs (PRM 26-1) from one year to three years. The comments received generally supported the proposed amendments and did not raise any significant technical issues. However, the application of the Backfit Rule to this rulemaking process continues to stimulate a broad spectrum of opinions and comments. These revised requirements will reduce the industry-wide annual cost for all licensees to comply with Part 26 by approximately \$27 million (or about \$285 million over 20 years).

The staff resubmitted the final FFD rule (SECY-99-279) to the Commission on December 6, 1999. By staff requirements memorandum dated July 5, 2000, the Commission returned SECY-99-279 to the staff. The Commission requested that the staff modify the FFD rulemaking package as follows: 1) remove the requirement imposing a more restrictive temperature range for an acceptable urine specimen (Sections 2.4(g)(13) and (15) of Appendix A) and 2) remove the requirement that a medical determination of fitness be performed to evaluate all employees tested for cause, including those who test negative, from the rulemaking package. In addition, the Commission directed that the staff should, in coordination with OGC, modify the analysis on compliance with the Backfit Rule to consider all the changes separately, and also in the aggregate, including those previously proposed as "worthwhile" changes. The current rulemaking package has been modified as directed by the Commission.

CATEGORY:

This paper covers issues requiring Commission consideration and decision

BACKGROUND:

When the Commission approved the first FFD rule for publication in the Federal Register, it recognized that the FFD program was a new and evolving discipline. The Commission directed the staff to monitor and review implementation of the rule, and recommend changes that might be needed (SRM of March 22, 1989).

The staff's interactions with the Commission since then has culminated with the submittal of proposed amendments to the FFD rule in SECY-95-262. The proposed amendments were published in the Federal Register on May 9, 1996 (61 FR 21105).

Approximately 1100 public comments were obtained from 38 letters; a public meeting was held in Rockville, Maryland, on June 12, 1996; and the staff met with the Region I Fitness for Duty Association on May 16, 1996.

Written comments were received from the general public, a union local and a union international headquarters, the Nuclear Energy Institute (NEI), 17 power reactor licensees, 7 vendors, a law firm, 2 professional associations, the Department of Health and Human Services, and a State agency.

The final rule was submitted to the Commissioners on June 4, 1999 (SECY-99-141). However, SECY-99-141 was withdrawn to address three issues, which have been completed. One issue concerned the need for a discussion in the statement of considerations on

decommissioned plants. The statement of considerations (under Summary of Changes From Proposed Rule Revisions, 26.2(e) — Scope) now indicates that the issue of FFD applicability to decommissioning plants should not be addressed in the current FFD rulemaking. Rather, the issue of FFD applicability should be resolved as part of a decommissioning regulatory improvement initiative under which the staff will reassess the technical and regulatory bases for applicability of the Commission's 10 CFR Part 50 regulations for operating nuclear power plants. Therefore, the staff has withdrawn the proposed amendment to 10 CFR 26.2(e) to allow the scope of FFD programs to be reduced for facilities that are being decommissioned as deemed appropriate by the NRC. A second issue was to satisfy Office of Management and Budget (OMB) clearance requirements. An OMB clearance package (Attachment J) has been completed. A third issue was to discuss in the statement of considerations one of several requests by Virginia Power in a petition for rulemaking (PRM 26-1) to change the audit frequency of FFD programs from one to two years. In response to PRM 26-1, 10 CFR Part 26.80 has been clarified to require that licensees conduct audits as needed “but no less frequently than every 36 months.” The petitioner’s additional requests (PRM 50-59 and PRM 50-60) were granted in a rule titled “Frequency of Reviews and Audits for Emergency Preparedness Programs, Safeguards Contingency Plans, and Security Programs for Nuclear Power Reactors” (64 FR 14814).

DISCUSSION:

Attachment A contains the Federal Register notice for the final rule. Attachment B shows the text of the final rule. Commenters did not raise any significant technical issues; however, they did raise substantial issues on backfitting that are discussed below under “Backfitting Considerations.” Commenters suggested many modifications to the proposed rule, several of which the staff recommends that the Commission adopt. These modifications that the staff recommends be adopted and their rationale are discussed in Attachment C. That attachment also addresses other modifications suggested by commenters that the staff recommends not be adopted. All public comments received are summarized in Attachment D, including the responses recommended by the staff.

The regulatory analysis, Attachment E, has had minor revisions from the analysis that was a part of SECY-95-262. The analysis indicates that the revised requirements will result in an industry-wide annual cost of approximately \$856,000, which is offset by an industry-wide annual savings of approximately \$27 million.

BACKFITTING CONSIDERATIONS:

The backfitting discussion in the SOC for the final rule contains a Commission determination that the revisions *in the aggregate* provide a substantial increase in the assurance of public health and safety. However, the rulemaking package continues to include the backfitting discussion of individual changes in the final FFD rule which are contained in the “Analysis of the Application of the Backfit Rule to the Revisions of the Fitness-for-Duty Rule (10 CFR Part 26).” That document (Attachment F) provides the basis for the overall Commission evaluation of the aggregate benefits of the final FFD rule.

RESOURCES:

NRC resources to implement the modified rule are estimated to be 0.5 FTE to revise program oversight and guidelines, that will be accomplished within current budgeted resources.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

The ACRS and the CRGR recommend issuance of the proposed final revisions to 10 CFR Part 26, as described in the proposed Federal Register notice (Attachment A). NRR categorized the following four revisions to the FFD rule as compliance exceptions:

- §2.7(f) of Appendix A to 10 CFR Part 26 (conforming the marijuana screening cutoff level);
- §2.7(e) of Appendix A to 10 CFR Part 26 (determination of specimen validity);
- §26.24(e) (limit time between notification and collection); and
- §26.22(c) (complete training of contractor supervisors not later than 10 days of initial supervisory assignment).

Rather than compliance exception, CRGR recommended that the revisions described in §2.7(f) of Appendix A, 26.24(e) and 26.22(c) be categorized as backfits and that § 2.7(e) of Appendix A be categorized as either a backfit or worthwhile change. Notwithstanding, NRR and OGC conclude that the compliance exception is the appropriate application of the Backfit Rule in each of these cases and is legally defensible (Appendix A to Attachment F).

All other CRGR recommendations have been adopted.

The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

The Office of the Chief Information Officer has reviewed the final rule for information technology and information management implications and concurs in the rulemaking.

The Office of Nuclear Reactor Regulation, the Office of Administration, the Office of Enforcement, and the Office of Nuclear Material Safety and Safeguards have concurred in this Commission Paper.

The Office of the Inspector General has been provided a copy of the Commission Paper.

RECOMMENDATIONS:

That the Commission:

1. Approve the final rulemaking for publication in the *Federal Register* (Attachment A);
2. Certify that this final rule will have no negative economic impact on a substantial number of small entities to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b). This certification is included in the attached Federal Register notice;

3. Determine that the revisions in the aggregate provide a substantial increase in protection to public health and safety;
4. Determine that the staff's responses to public comments (Attachment D) are acceptable; and
5. Approve that the rule becomes effective 90 days after the date of publication in the Federal Register.
6. NOTE THAT:
 - a. The final rule as set forth in the Federal Register notice (Attachment A) will be published and posted on the NRC website.
 - b. The staff has determined that the final rule is the type of action described in categorical exclusion, 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental impact assessment has been prepared for the final rule.
 - c. A regulatory analysis (Attachment E) has been prepared and will be placed in the NRC Public Document Room and posted on the NRC web site.
 - d. Copies of the Federal Register notice of the final rule will be distributed to all licensees as well as to commenters on the proposed rule. The notice will be sent to other interested parties upon request.
 - e. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it as required by the Regulatory Flexibility Act.
 - f. This rulemaking has been reviewed pursuant to the Small Business Regulatory Enforcement Fairness Act and is not a "major" rule, as defined by the Act. The appropriate form will be sent to the General Accounting Office (Attachment G).

- g. The information collection requirements in the proposed rule have been approved by OMB, and the additional information collection requirements in the final rule are subject to review and approval by OMB. The staff will not publish the final rule until the OMB clearance has been received. If OMB requires any substantive changes, the staff will obtain Commission approval before publishing the final rule.

/RA/

William D. Travers
Executive Director
for Operations

- Attachments: A. Federal Register Notice of Final Rulemaking
B. Text of Rule
C. Listing of Recommended Modifications to Proposed Revisions
D. Responses to Public Comments
E. Final Regulatory Analysis
F. Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule
G. Form to GAO
H. OMB Clearance Package

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***SEE PREVIOUS CONCURRENCE.**

DOCUMENT NAME: G:\IOLB\IRSS\WEST\Final Fitness For Duty Rule\Final FFD Rule Per SRM of July 5_ 2000_to_EDO.WPD

OFFICE	RSS:DIPM	RSS:DIPM	IOLB:DIPM	DRIP:NRR	PPRB: NRR	D:DIPM
NAME	G West*	RP Rosano*	G Tracy*	C Carpenter via e-mail	M Case*	BA Boger*
DATE	7/12/00	7/13/00	7/13/00	7/17/00	7/14/00	7/14/00
OFFICE	ADT:NRR	D:NRR	OGC	OCIO	ADM	EDO
NAME	J Johnson	S Collins	S Treby*	B Shelton via e-mail	D Meyer*	WD Travers
DATE	7/17/00	7/17/00	7/14/00	07/17/00	7/14/00	07/26/00

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ATTACHMENT A
FEDERAL REGISTER NOTICE

NUCLEAR REGULATORY COMMISSION
10 CFR Part 26
RIN: 3150-AF12
Modifications to Fitness-For-Duty
Program Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is revising its regulations that establish its Fitness-For-Duty Program (FFD) requirements. These requirements apply to all licensees authorized to construct or operate a nuclear power reactor and all licensees authorized to possess or transport Category I nuclear material. The general objective of this program continues to be to provide reasonable assurance that nuclear power plant and nuclear fuel facility personnel are reliable, trustworthy, and not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, that in any way may adversely affect their ability to safely and competently perform their duties. This final rule also grants one of several requests by Virginia Power in a December 30, 1993 petition for rulemaking (PRM) to change the licensee audit frequency of FFD programs (PRM-26-1) from one year to two years.

EFFECTIVE DATE: (Insert 90 days from date of publication in the Federal Register).

FOR FURTHER INFORMATION CONTACT: Dr. Garmon West, Jr., Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone: (301) 415-1044, e-mail: fitnessforduty@nrc.gov or Richard P. Rosano of the same address, telephone: (301) 415-2933, e-mail: fitnessforduty@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

The NRC published a final rule, "Fitness-for-Duty Programs," in the Federal Register on June 7, 1989 (54 FR 24468). The rule required each licensee authorized to operate or construct a nuclear power reactor to implement a Fitness-for-Duty Program for all personnel having unescorted access to the protected area of its plant. This rule became effective on July 7, 1989, with an implementation date of January 3, 1990. A subsequent final rule published on June 3, 1993 (58 FR 31467) expanded the scope of Part 26 to include licensees authorized to handle Strategic Special Nuclear Materials (SSNM). This rule became effective on November 30, 1993.

When the rule was published in 1989, the Commission directed the NRC staff to continue to analyze licensee programs, assess the effectiveness of the rule, and recommend appropriate improvements or changes. The NRC staff reviewed information from several sources including inspections, periodic reports by licensees on FFD program performance, reports of significant FFD events, industry sponsored meetings, initiatives by the Nuclear Management and Resources Council (NUMARC) (now the Nuclear Energy Institute [NEI]), and the Substance Abuse and Mental Health Services Administration (SAMHSA) (formerly the

National Institute on Drug Abuse [NIDA]), and its Drug Testing Advisory Board, and current literature. Program Performance Reports submitted by licensees indicate that from the effective date of the Fitness-for-Duty (10 CFR Part 26) rule in January 1990 through the end of December 1999, there were 15,583 positive test results. During this period, the rate of positives per year were as follows: 0.87%, 0.66%, 0.68%, 0.62%, 0.84%, 0.98%, 1.03%, 0.97%, 0.87%, and 0.96%. Pre-access testing identified 10,676 applicants as positive, and 4,907 workers with unescorted access to the protected area tested positive for illegal drugs or alcohol. During the same period, 103 licensed operators, 163 licensee supervisors, and 141 contract supervisors violated a licensee's FFD policy.

A review of FFD program experience and the public comments on the proposed amendments confirmed that the regulatory approach included in 10 CFR Part 26 is fundamentally sound and continues to provide a means of deterrence and detection of substance abuse at licensee facilities. Nonetheless, it was determined that a revision was needed to:

- (1) Ensure compatibility with changes to the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs [published in the Federal Register on June 9, 1994 (59 FR 29908), and September 30, 1997 (62 FR 51118)];
- (2) Reduce the burden on licensees while fulfilling the rule's purpose;
- (3) Clarify requirements promulgated in the original rule to reduce incorrect or inconsistent use and differing interpretations and to make a number of administrative changes;
- (4) Modify requirements to ensure compliance with all aspects of the original rule and the clearly stated intent of the Commission when it adopted the original requirements.

The NRC published for public comment proposed modifications to the current FFD requirements on May 9, 1996 (61 FR 21105). The proposed amendments did not include major changes to the rule. They did, however, propose to increase compatibility with the HHS Mandatory Guidelines; substantially reduce licensees' cost of implementing the rule; enhance overall program integrity, effectiveness, and efficiency; and help to ensure the continued protection of public health and safety. The 90-day public comment period for the proposed rulemaking closed on August 7, 1996.

Abbreviations

The following abbreviations and acronyms are used in the Statement of Considerations of this Federal Register notice.

BAC	Blood alcohol concentration
CLIA	Clinical Laboratory Improvement Amendments of 1988
DOT	Department of Transportation
FDA	Food and Drug Administration
FFD	Fitness for Duty
GC/MS	Gas chromatography/mass spectrometry
HHS/DHHS	Department of Health and Human Services
LOD	Limit of detection
MRO	Medical Review Officer
NEI	Nuclear Energy Institute
NIDA	National Institute on Drug Abuse
NLCP	National Laboratory Certification Program
NRC	U.S. Nuclear Regulatory Commission
NUMARC	Nuclear Management and Resources Council
OMB	Office of Management and Budget
pH	potential of hydrogen

QA/QC	Quality assurance/quality control
SAMHSA	Substance Abuse and Mental Health Services Administration
SSNM	Strategic special nuclear material
THC	Tetrahydrocannabinol
6-AM	6-acetylmorphine

Availability of Referenced Documents

Copies of the Regulatory Analysis, the Responses to Public Comments—Fitness for Duty in the Nuclear Industry: Responses to 1996 Public Comments, the Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule, NLCP Program Document #35, the Staff Requirements Memorandum (SRM) of June 30, 1993 (SECY-93-086), and the HHS Technical Advisory of March 11, 1991, are available for public inspection and copying for a fee at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

Copies of NUREG/CR-1354, “Fitness for Duty in the Nuclear Power Industry: Responses to Public Comments” (1989), and NUREG-1385, “Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions: (1989) may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328. Copies are also available from the National Technical Information Service, 5282 Port Royal Road, Springfield, VA 22161. A copy is available for inspection and/or copying in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

Summary of Public Comments and NRC Responses

Written public comments were provided in 38 comment letters, of which four were from the general public including one NRC employee, one from a union local and one a union international headquarters, one from the Nuclear Energy Institute (NEI), 17 from power reactor licensees, two from fuel facility licensees, seven from vendors, one from a law firm, two from professional associations, one from the U.S. Department of Health and Human Services (HHS), and one from a State agency. In addition, comments were received during a public meeting which was held in Rockville, MD, on June 12, 1996, and from a meeting with the Region I Fitness for Duty Association which was held in Hancocks Bridge, NJ, on May 16, 1996. Copies of the letters, a transcript of the June 12, 1996, public meeting, and a list of questions posed at the May 16, 1996, meeting in Region I are available for public inspection and copying for a fee at the Commission's Public Document Room, located at 2120 L Street, N.W. (Lower Level), Washington, D.C.

The NRC carefully reviewed and considered the comments received and has made changes to some of the proposed modifications. Minor administrative changes throughout the rule also have been made. A summary of those comments addressing the more significant issues and NRC's responses is provided below. A summary of the substantive changes from the rule revisions that were proposed on May 9, 1996 (61 FR 21105), is also provided.

1. *Responses to NRC Questions.*

In the proposed rule, the NRC solicited public comment on eight specific issues regarding new or changed requirements that the NRC was considering. Several commenters responded. In addition to these eight questions, the NRC posed additional questions in the general discussion section of the Federal Register notice. Below are the NRC's specific questions, summaries of the public comments received in response to these questions, and the NRC's responses to the public comments.

NRC question 1(a): Would any of the proposed changes, groups of related requirements (e.g., modifications to prevent subversion of the testing process, further ensure the accuracy and integrity of testing, clarify actions for removal), or the rulemaking as a whole provide a substantial increase in the overall protection of the public health and safety or the common defense and security?

Summary of comments: Most commenters who responded to this question stated that the proposed changes, considered individually or as a whole, would not provide a substantial increase in the overall protection of the public health and safety. Three commenters stated that the changes as a whole would either provide an incremental improvement in the protection of the public health and safety or enhance the achievement of the objectives of the FFD program.

NRC response: The NRC has reevaluated the proposed changes in light of the public comments. As set forth below in the “Backfit Analysis” section, the Commission has determined that the FFD rule should be evaluated for backfitting as an integrated whole, and has concluded that the rule in the aggregate constitutes a cost-justified substantial increase in protection to public health and safety.

NRC question 1(b): Are the groupings and subgroupings of the changes contained in the Backfit Analysis section of the Federal Register notice appropriate and are the changes categorized properly?

Summary of comments: While not referring explicitly to the Commission’s categorization of the proposed rule changes, several commenters expressed the opinion that most of the proposed changes would create reasonable and appropriate clarifications of rule requirements or reductions of licensee burden and should be adopted as soon as possible. Several commenters, however, said that proposed revisions that would increase licensee burden should be subject to backfit analysis. Several commenters expressed the opinion that the backfit rule applies only to new obligations imposed by the NRC. One of these commenters specifically said that it is the mandatory nature of the regulatory change that controls applicability of the backfit rule, and that, where a reduction in a regulatory requirement or the implementation of a revision is not made mandatory, but is instead left to licensees’ discretion to continue implementing the current requirement or adopt the change, such changes are not backfits.

NRC Response: The NRC has thoroughly reviewed all of its proposed revisions with respect to the application of the backfit rule and has concluded that each revision fits into at least one of the following classifications, as discussed in the “Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26):”

- 1) Clarifications. Several revisions will clarify current requirements to assure consistent understanding and implementation of the Commission’s original intent for these requirements. Without changing the requirements stated in these sections, these revisions would remove the ambiguities that produced the licensee’s uncertainty. The backfit rule does not apply to revisions that leave current requirements unchanged.
- 2) Administrative matters. A few revisions make minor administrative changes, such as correction of typographic errors, correction of inconsistencies, relocating requirements from one section to another, and combining existing requirements into a single section. Administrative matters are not subject to the Backfit Rule requirements.

- 3) Permissive relaxations. Several revisions permit, but not require, relaxations of current requirements (i.e., licensees are free to either comply with current requirements or adopt the relaxed requirements as an alternative). The backfit rule does not apply to rule revisions that provide permissive relaxations of current requirements.
- 4) Information collection and reporting requirements. A few revisions modify information collection and reporting requirements, which are not considered to be subject to the Backfit Rule.
- 5) Compliance exceptions. Several revisions are necessary to bring licensees into compliance with existing Commission requirements or the Commission's clearly stated intent in promulgating the requirement. In addition, some of the revisions modify current requirements where there is evidence that the current version of the standard is not achieving the purpose that the Commission had when it originally promulgated the rule. These revisions are exceptions to the backfit rule, as specified in 10 CFR 50.109(a)(4)(I).
- 6) Worthwhile changes to be adopted as Backfit Rule Exceptions. Some of the revisions are recommended for consideration for adoption as an exception to the backfit rule because they are worthwhile changes. The Commission indicated in the SRM dated June 30, 1993, that it would consider worthwhile changes on a case-by-case basis as an exception to the "substantial increase" in safety standard, as long as they have been subject to public notice and comment, as these revisions have.

However, as set forth below in the "Backfit Analysis" section, the Commission has determined that the FFD rule should be evaluated for backfitting as an integrated whole, and has concluded that the rule in the aggregate constitutes a cost-justified substantial increase in protection to public health and safety.

NRC question 1(c): Are the changes in Group III worthwhile and necessary to better accomplish the FFD rule's objective, clarify the rule's existing requirements, and reduce ambiguities?

Summary of comments: Although commenters did not specifically refer to the Commission's categorization scheme, some commenters supported the Commission going forward with those rule revisions that serve to better accomplish the rule's objectives and clarify current requirements. One commenter stated that the proposed revisions would significantly improve the effectiveness of the FFD program and that the backfit rule should not apply to this rulemaking. The remainder of these commenters stated that the backfit rule requires the NRC to conduct an analysis of the effects of those revisions that would create new licensee burden.

NRC response: The NRC has prepared a detailed analysis of the backfitting applications of each of the proposed changes, which may be found in the "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26)."

NRC question 1(d): Do the rule revisions as a whole not constitute a backfit since the rule's cumulative effect is to ease licensee burdens or leave them essentially the same rather than to increase them?

Summary of comments: One commenter recommended that the backfit rule should not be applied to the proposed amendments because the rulemaking as a whole would provide an incremental improvement and reduce licensee burden. Another commenter contended that the proposed revisions would significantly improve the effectiveness of the FFD program and that the backfit rule should not apply to this rulemaking. This commenter justified that contention by

observing that drug abuse is a chronic and dynamic problem and that, rather than remaining static, FFD programs must keep pace with changes in drug abuse patterns, methods of drug detection avoidance, and new technologies. Therefore, this commenter stressed that technical changes to FFD programs are essential to maintain effectiveness. The commenter also asserted that the backfit analysis requirement is an obstacle to maintaining effectiveness, the backfit rule essentially requires that the FFD program has to come close to being ineffectual before regulatory changes can be made, and that safety programs should not have to run to the brink of failure before corrective action can be taken.

Other commenters urged the Commission to proceed with adopting those revisions that would not increase burden and to justify those revisions that would increase burden with a backfit analysis. Some commenters expressed the opinion that most of the proposed changes would create reasonable and appropriate clarifications of rule requirements or reductions of licensee burden and should be adopted as soon as possible. These commenters stated that adoption of these changes does not require an exception to the backfit rule because no new burden would be imposed on licensees. Several commenters stated that the backfit rule applies only to new obligations imposed by the NRC. One commenter stated that it is the mandatory nature of the regulatory change that controls applicability of the rule. If a reduction in a regulatory requirement or the elimination of a regulation is not made mandatory but is instead left to licensees' discretion whether to continue implementing the current requirement or adopt the change, the change is not a backfit.

NRC response: The NRC agrees with the commenters that the backfit analysis requirement does not apply to specific revisions that either relax current requirements, are neutral with respect to current requirements, or that clarify, but do not change, existing FFD program requirements.

NRC question 1(e): Does anyone subject to the rule not object to the new requirements in view of their perception of an overall benefit and, if so, would their non-objection be grounds for not applying the backfit rule?

Summary of comments: The one commenter who addressed this specific question stated that the NRC's authority to waive the backfit rule is limited and that a backfit analysis should be performed for any new requirement meeting the definition of a backfit. Although not specifically addressing this question, other commenters stated in general terms that the NRC must apply backfit analysis to those proposed revisions that would increase licensee burden even if the overall effect of the revisions would be to decrease burden.

NRC response: Since there were commenters subject to the rule who objected to some of the new requirements, the NRC will not rely upon a "non-objection" as a basis for not applying the Backfit Rule.

NRC question 1(f): Although the NRC believes that the proposed specific changes to the FFD rule would be the most efficient method of accomplishing the regulatory objectives of the changes, are there any viable alternative approaches that should be considered, particularly with respect to the proposed changes in Group III B?

Summary of comments: One commenter stated that the proposed amendments are the most efficient method of accomplishing the regulatory objectives and alternatives, such as regulatory or industry developed guidance, would not solve existing regulatory problems. Another commenter supported the development of industry-sponsored guidance based upon discussions between the NRC staff and industry representatives. This commenter also stated that, if Part 26 were to become more performance based, then industry guidelines would be

appropriate and probably necessary. Another commenter urged the NRC to examine other vehicles such as a regulatory guide or generic letter. One commenter stated that many of the proposed amendments are unnecessary and did not believe that the need for additional requirements had been sufficiently established while another commenter did not agree that the proposed revisions would reduce the cost of implementation, enhance program integrity, effectiveness, and efficiency and help ensure the continued protection of public health and safety in the most efficient and effective way. However, these two commenters did not suggest alternatives.

NRC response: After consideration of alternative approaches suggested by commenters, the NRC has concluded that rulemaking is the only effective vehicle for making these changes. Rule change is favored because it may reduce interpretive debates. Collective bargaining and judicial reviews also require clear public policy that is provided by rulemaking. The NRC's earlier experience with industry-developed FFD testing guidelines used to implement an NRC policy statement was unsatisfactory, mostly because of these impediments, and was the primary reason the Commission developed Part 26.

NRC question 1(g): Could the rule be less specific in stating the requirements?

Summary of comments: One commenter expressed an opinion that the level of specificity in stating the requirements is appropriate and needed as discussed in the May 9, 1996 Federal Register notice beginning at 61 FR 21106.

NRC response: The NRC agrees with the commenter. The past seven and one-half years of program implementation have indicated the need for the FFD rule to be quite specific in establishing several FFD program requirements. The many questions as to the meaning of certain rule sections plus continuing licensee FFD program administrator requests of the NRC staff for other guidance attest to the need for this level of specificity. The NRC is also aware, however, that licensee programs can be most effective in fulfilling some FFD program requirements if they have the flexibility to find the most effective and efficient means of meeting those requirements. In some cases, the NRC has relaxed the rule's specificity to allow needed flexibility. The NRC has taken both of these considerations into account and has adopted the revisions to the FFD rule.

NRC question 2: Should the NRC revise Appendix A to 10 CFR Part 26 to incorporate revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs adopted by the Department of Health and Human Services (HHS) (June 9, 1994; 59 FR 29908)? The Commission proposes adoption of the changes to the HHS Mandatory Guidelines. In most instances, the HHS Mandatory Guidelines have been adopted as published by HHS; however, in some cases modifications are proposed to allow compatibility within the framework of the original FFD rule (e.g., onsite testing provisions dictated differences in minimum specimen volume, minimum number of blind performance specimens, onsite determination of the validity of specimens). The NRC desires to be consistent with the HHS Mandatory Guidelines, absent a compelling reason why a departure is necessary.

Summary of comments: Several commenters agreed that the revisions to the HHS Mandatory Guidelines should be incorporated to maintain consistency between Part 26 and the HHS requirements; however, many qualified their responses. One commenter recommended that the NRC adopt modifications to some of the HHS Mandatory Guidelines revisions to allow compatibility with the original FFD rule. Another commenter stated that licensees should be allowed to adopt additional or more stringent requirements as appropriate for their own circumstances. A third commenter stated there should not be any differences between the

HHS and NRC requirements and that the NRC should automatically adopt all future revisions to the HHS Mandatory Guidelines into Appendix A of Part 26 so that nuclear industry testing would be consistent with the recommended Federal testing process used by other regulatory agencies. Another commenter stated that changes to ensure compatibility with the HHS Mandatory Guidelines would provide consistency with other Federal programs. One commenter noted that there are major differences between the policies proposed by the NRC and those included in the HHS Mandatory Guidelines. To reduce potential confusion, this commenter recommended that the NRC refer only to the parts of the HHS Mandatory Guidelines that it wants to accept, rather than stating that it wants to be consistent and then allow changes to the HHS requirements. The commenter cited the fact that the NRC directs licensees to use the HHS chemical testing cut-off levels but also allows licensees to use different levels as an example of this seeming inconsistency.

NRC response: The NRC concurs with the commenters' views as to the value of providing consistency with the HHS Mandatory Guidelines revisions to the extent practical, while acknowledging the need to make adjustments to some of the HHS Guidelines revisions to respond to the requirements specific to the nuclear industry's needs. The NRC believes that consistency across Federal programs is desirable when practicable. However, the NRC concludes that some differences between Part 26 requirements and those of other Federally mandated programs are necessary. While much of the HHS Mandatory Guidelines has been adopted as published by HHS, the NRC has made some modifications to achieve compatibility with the NRC's responsibilities for assuring public health and safety and to address and/or accommodate issues which are specific to the nuclear power industry. Adoption of a procedure that would automatically incorporate changes to the HHS Mandatory Guidelines would not allow the consideration of issues specific to the nuclear power industry.

NRC question 3: With respect to the discussion of the proposed changes to section 26.24, are there any alternative techniques for testing for alcohol that should be considered for adoption by the NRC?

Summary of comments: Several commenters stated that at this time they are aware of no alternative alcohol testing techniques that appear to be superior to the National Highway Traffic Safety Administration (NHTSA)-approved evidential-grade breath analysis equipment that the FFD rule has always required. A few commenters recommended that the NRC relax its current requirements by approving the use of non-evidential breath testing devices for alcohol screening testing. Another commenter noted that court decisions have approved the use of NHTSA-approved evidential breath testing and that, even if the use of other equipment for screening testing was allowed, evidential-grade breath analysis equipment would still be needed to achieve legally recognized confirmatory testing.

Commenters also made other specific recommendations regarding alcohol testing procedures. One commenter thought blood testing for alcohol to be unnecessary and recommended that it be eliminated from the rule or allowed only in extreme cases (e.g., post-accident testing when individual is unconscious). Another commenter requested that the NRC consider devices which use two independent testing technologies (electro-chemical fuel cell and 9.5 micron infrared spectroscopy) for use in confirmatory testing or for both screening and confirmatory testing.

NRC response: The NRC believes that the current requirements for use of evidential devices that conform to NHTSA's Model Specifications for Evidential Breath Testing Devices (September 17, 1993; 58 FR 48705 and December 14, 1984; 49 FR 48854) are appropriate for

both screening and confirmatory tests. Part 26 will continue to require the use of these devices. All NRC-regulated programs currently have these devices in use.

The approval of non-evidential testing devices by the U.S. Department of Transportation (DOT), for example, provides more flexibility for initial testing due to the nature of the industry it regulates, which requires more mobile testing mechanisms. This mobility is generally not an issue in NRC-regulated programs.

The NRC is satisfied with the current requirements and the devices on NHTSA's Conforming Products List (CPL) for evidential devices that conform to the model specifications (a CPL update was published on January 30, 1996; 61 FR 3078). The development of the CPL by NHTSA includes the evaluation of devices which use two independent testing technologies. The NRC sees no need for it to additionally evaluate such devices. Furthermore, the NRC believes that the use of non-evidential grade equipment may lead to false negative test results. Therefore, the alcohol screening procedures have not been changed to permit use of non-evidential grade equipment.

The NRC recognizes the difficulties associated with blood collection but continues to believe that the opportunity for blood testing provides people covered by Part 26 requirements with desirable reassurance regarding their appeal rights. It also increases the legal defensibility of all positive alcohol results, including those appealed without the drawing of blood.

NRC question 4: During the past 5 years of program operations, several parties have recommended that the NRC consider obtaining certain types of information in addition to that currently required to be submitted under the provision of section 26.71(d). They believe that the Commission could use such information to better manage its FFD program oversight responsibilities, which includes formulation of public policy. The specific additional types of information and their potential use by the NRC were described in the discussion of proposed revisions to section 26.71 but are not incorporated into the proposed changes to the text of the rule. The NRC requested public comment on whether licensees should be required to collect, analyze, and submit to the NRC such additional types of information.

The NRC also noted in another section of the discussion that having access to this information would enable the NRC to gain a clearer and more detailed understanding of the actual operation of the programs. This information would also be useful for purposes of revising the regulation or providing guidance so that the general performance objectives stated in § 26.10 can be better achieved. The NRC, therefore, also sought public comment as to whether § 26.71(d) should be revised further to require that these types of information be collected and analyzed by licensees and submitted to the NRC. The NRC also sought public comment as to whether the NRC should develop a management information system similar to that issued by DOT and its operating administrations (see December 23, 1993; 58 FR 68194 through 68285).

Summary of comments: One commenter stated that there is no demonstrated value added and no potential improvements derived if the NRC collects additional information, and that requiring unnecessary data may be contrary to employee assistance program (EAP) confidentiality and the Paperwork Reduction Act. Another commenter stated that the proposed data collection is in conflict with confidentiality of EAPs and is not a deterrent to drug and alcohol use. Two commenters stated that there should not be requirements for additional data unless there are specific benefits identified such as an increase in protection of public health and safety or the information can be used by the utilities. Two commenters stated that the added administrative burden would be costly and not effective. Two commenters stated that the additional information would not increase overall protection of the public health and safety.

Another commenter stated that the information can be made available during inspections and that the value added does not warrant the additional burden to the licensees.

NRC response: The NRC has decided not to add requirements for additional information to be routinely collected at this time beyond the types of additional information that it originally proposed. The NRC may in the future decide to collect information of the type discussed in the proposed rule for purposes of developing program performance indicators. The proposed clarification of significant FFD events that must be reported and the addition of subversion attempts to program performance reports will be retained in the final rule.

NRC question 5: The NRC is proposing to add a new section 2.7(e) to Appendix A that would require testing to determine specimen validity (i.e., detect evidence of adulteration or dilution) before performing a screening test on site (if appropriate) and at the HHS-certified laboratory. This would be an adaptation of a change HHS made to its Mandatory Guidelines in June 1994. However, not all dilute specimens are the result of attempts to avoid detection. Hence, to minimize the probability of incorrect conclusions from such events, suspect specimens, including those with abnormal specific gravity (SG), would be subject to screening and confirmation testing using the limit of detection that the laboratory is capable of performing. The Commission requested comments regarding this change and, in addition, requested comments on three other proposed revisions to detect evidence of adulteration or dilution:

Summary of comments: The comments responding to the proposed revisions regarding testing for specific gravity and at laboratory limits of detection (LOD) included a wide range of issues. Several commenters opposed these changes, citing increased costs, problems with the technical defensibility of the procedure, problems of cross-contamination during testing, and differences in LOD standards among laboratories that may cause inconsistent test results, and contended that HHS does not sanction the procedure. Other commenters supported the new requirements and offered suggestions regarding improvements in implementation and/or suggestions for additional tests for specimen validity, such as pH and creatinine testing. Supporters noted that the rule has always required specimen validity testing and that clearer guidelines would increase consistency and decrease successful subversion. Several commenters requested information regarding whether the addition of specific gravity testing would affect the application of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to licensee testing programs. Both positive and negative comments were also received regarding testing at LOD. Commenters opposing the policy cited concerns about increased costs, the technical defensibility of the procedure, problems with cross-contamination during testing, desire for HHS guidance, and the potential that inter-laboratory differences in standards may create legal difficulties. Supporters of LOD testing noted that it was currently being used under the HHS, NRC, and DOT testing guidelines for retesting of specimens.

NRC response: The NRC appreciates the time and care that commenters took to respond to this question. Although specimen validity testing has always been included in Part 26 (see sections 2.1(e), 2.4(g), and 2.7(d) of Appendix A), the NRC has determined that there are substantial benefits of providing minimum requirements for this testing and has decided to adopt changes made to the HHS Mandatory Guidelines and changes to laboratory procedures directed by HHS under its National Laboratory Certification Program (NLCP). NLCP Program Document #35 establishes standards for the HHS certified laboratories to conduct tests for creatinine, specific gravity, pH, and nitrites to detect evidence of adulteration and dilution. These standards for determining specimen validity will increase consistency, decrease successful subversion, and will deter attempts to subvert the testing process through specimen adulteration and dilution.

Studies of the relationship between dilution and the presence of drug metabolites at or below cut-off levels indicate that, while dilute specimens are approximately ten times more likely to be positive, ninety percent of dilute specimens show no evidence of illegal drug use. In making this revision, the NRC is attempting to strike a balance that will maximize detection and deterrence of attempts to subvert the testing process through dilution while minimizing the impact on individuals who have dilute specimens for legitimate reasons. Testing of questionable specimens to identify lower concentration levels of drug or metabolite is intended to achieve both purposes. If a questionable specimen is found to contain illegal drugs or metabolites at the lower level of concentration, it is a violation of the licensee's FFD policy. No additional testing is necessary for this conclusion. (The MRO may determine in these situations both that the donor has attempted to subvert the testing process and used illegal drugs.) If the questionable specimen is negative at the lower level of concentration, the MRO has the option of determining that it is a true negative and reporting it as such, or of determining that there is still a question and more information (potentially including an observed recollection) is required.

In conjunction with these changes, the NRC believes it is appropriate to remove the requirement for recollection under direct observation in all cases where a specimen is found to be dilute. The process for determining specimen validity in a new section 2.7(e) of Appendix A will result in most specimens being determined to be either valid or invalid. When the MRO cannot determine if the specimen is valid or invalid, another specimen must be collected as soon as possible.

In response to commenters' discussion of difficulties and suggestions, the NRC has modified the LOD testing requirement as originally proposed. The modified requirements call for screening tests of specimens of questionable validity, e.g., that contain no detectable adulterants but show evidence of dilution by having creatinine, specific gravity, and pH values between a valid specimen and an invalid specimen. Those specimens that have responses that are greater than the negative control responses to the screening tests are to be tested with GC/MS at the laboratory's LOD. This change makes the process for testing specimens with questionable validity comparable to the process for the testing of valid specimens. Although the MRO will still review the results of tests of all specimens of questionable validity, under this change the MRO, with the additional evidence of no drugs found with LOD processing, may determine that there is no need for an observed specimen collection. Related comments and responses are discussed in sections 21 and 22 below.

NRC question 5(a): Including pH and/or creatinine as well as SG in the required testing to determine specimen validity;

Summary of comments: Some commenters noted that creatinine testing would be difficult on site. Others suggested the NRC establish specific levels for creatinine and pH testing.

NRC response: Tests for creatinine, SG, pH, and nitrites are means of determining specimen validity. The NRC will, consistent with actions taken by HHS in NLCP Program Document #35, require testing for creatinine, SG, pH, and nitrites to determine specimen validity at the HHS-certified laboratories. The NRC will require testing for creatinine, SG, pH, and nitrites for specimens being tested on site. Onsite testing for these specimen characteristics may be accomplished by "dipsticks."

NRC question 5(b): Requiring tests to determine specimen validity (which might include SG, pH, and/or creatinine) immediately after specimen collection at all sites and immediate

collection of a second specimen from those individuals providing specimens with abnormal qualities;

Summary of comments: One commenter responded directly to this question, suggesting that specimen validity should be conducted at the time of the collection whenever practical. Another commenter objected to immediate collection of a second specimen because there are many reasons other than attempted subversion for providing a dilute specimen.

NRC response: The NRC has chosen not to require testing for specimen validity at licensees' collection facilities and immediate collection of a second specimen when a person submits a specimen with abnormal qualities. (The basis for immediate recollections are listed in § 2.4(g)(15)(ii).) Instead, specimen validity testing is to be conducted at licensees' testing facilities (for licensees performing onsite testing) and at HHS-certified laboratories for all specimens sent to the laboratories.

NRC question 5(c): Requiring tests at one-half of the cut-off levels specified for each drug instead of at the HHS-certified laboratory's limit of detection for suspect specimens.

Summary of comments: There were several comments related to whether the NRC should require testing at one-half the standard cut-off levels for suspect specimens. Two commenters disagreed with the proposal. One commenter recommended that the LOD be used for all testing and that it should be the standard (in essence, eliminating cut-off levels from the rule). Another commenter recommended that laboratory screening continue to be conducted at licensee-determined screening levels with the HHS Mandatory Guideline levels serving as maximum cut-off levels.

NRC response: The NRC concurs that the LOD levels achieved by each HHS-certified laboratory should be used for suspect specimens rather than one-half the cut-off levels specified by HHS for each drug. Because there is not an LOD for screening testing, the rule will now require that screening testing for suspect specimens include comparison to negative screening controls. Although LOD results are technically accurate and could be used for all testing, cutoff levels will continue to be used as a matter of policy to minimize the possibility of cross reactivity, passive inhalation, and similar challenges to the accuracy of test results. Furthermore, GC/MS testing, which would be needed for LOD testing, is quite expensive and is not needed when a less expensive screening test can accurately determine that a specimen is clearly negative.

NRC question 6(a): With respect to the discussion of the proposed changes to section 2.7 of Appendix A, should the NRC require tests for agents that can be added to urine as an attempt to mask THC (marijuana) or other drugs?

Summary of comments: The NRC received a number of comments regarding testing for agents that can be added to urine specimens to mask the presence of drugs or drug metabolites. Some commenters objected to any regulatory requirements for this testing, preferring that any testing be covered by industry guidelines. Other commenters recommended that, if this testing is deemed necessary, it should be mandated by HHS for HHS-certified laboratories rather than by the NRC. Still other commenters supported the proposed requirements for testing for masking agents.

NRC response: The NRC will not require, but will continue to allow, testing for masking agents. The NRC expects licensees to pursue reasonable means of determining whether specimens are valid for testing. While tests for specific masking agents provide detailed information regarding the basis for an invalid specimen, this information may not be needed to determine why a specimen is invalid. It is sufficient to determine that the specimen is not valid

and to impose sanctions based on that determination in accordance with the licensee's written policy.

NRC question 6(b): With respect to the discussion of the proposed changes to section 2.7 of Appendix A, should the NRC raise the cut-off levels for screening and confirmation tests for opiates to reduce the laboratory confirmed positives for opiates that the medical review officer (MRO) determines to be negative? Given the high level of concern for safety in the nuclear industry, should the NRC retain the current levels, even if HHS should raise the levels for “demand reduction” programs covered by its Mandatory Guidelines as it proposed on November 16, 1995 (60 FR 57587)?

Summary of comments: Many commenters responded to this question, expressing two clear and differing opinions. The opinion differences were not based on differences in interpretation of the empirical evidence, but instead were based on the appropriate basis for making a decision. One opinion focused on the high cost of the current cut-off levels. These commenters recommended adoption of the proposed higher cut-off levels for opiates and the additional criteria regarding the need for 6-acetylmorphine (6-AM) testing because of the relatively high number of confirmed positive laboratory test results at the current cut-off levels that MROs subsequently determine to result from legitimate use. Commenters having this view noted the high expense and low value in the work necessitated by these outcomes. The second opinion focused on the potential for false negative test results (i.e., opiate abusers not being detected) that higher cut-off levels for opiates would create. These commenters argued that the higher cut-off levels and 6-AM requirements proposed by HHS would virtually eliminate all positives for opiates except those resulting from heavy recent heroin use. This would prevent the detection of the use of opiates, such as codeine, in inappropriate ways (e.g., taking more than prescribed amounts or operating heavy equipment when taking a legally prescribed, but impairing, drug).

NRC response: The NRC has carefully considered the cost of opiate testing at the current levels and the potential cost relief represented by the proposed higher cut-off levels for opiates that, when the Commission published the proposed FFD rule revisions, were being proposed by HHS. (HHS has since formally adopted these higher opiate cutoff levels. See 62 FR 51118, September 30, 1997.) It has also carefully considered the potential risk to public health and safety posed by failure to identify opiate abuse. The NRC has determined that the protection of public health and safety necessitates the continued use of the current cut-off levels for opiates. This means that MROs will need to continue evaluating whether the presence of opiates, even if the specimen is not declared by the MRO to be a violation of the licensee's FFD policy, presents a potential safety risk. To eliminate unnecessary confirmatory tests, the NRC will adopt the HHS policy with respect to testing for 6-AM, which is based on the pharmacology of heroin metabolism, i.e., 6-AM is likely to be present only when morphine is present in the specimen and its concentration exceeds 2,000 ng/ml. Testing for 6-AM will be required only when confirmed morphine concentrations exceed 2,000 ng/ml.

NRC question 7: A key element of assuring the integrity of the testing program is the continued assurance of test accuracy through licensees' submission of blind performance test specimens to HHS-certified laboratories as required by section 2.8(e) of Appendix A. The NRC has received a number of suggestions regarding improving these blind performance test specimen requirements. The Commission was considering each of these suggested revisions and invited public comment on the following:

NRC question 7(a): A limited HHS survey of blind performance test specimens supplied by various vendors has indicated a wide range of drug or metabolite concentrations in spiked specimens. Should the NRC require licensees to assure that concentration ranges for blind performance test specimens be within a defined range (to be determined in consultation with HHS)?

Summary of comments: Three commenters stated that there is no reason or it is unnecessary for drug or metabolite concentrations in spiked specimens to be within a defined range. One of these commenters also noted that neither the NRC nor DOT regulations define the concentration levels of spiked blind performance specimens. The same commenter stated that, if the NRC requires blind performance specimens to be spiked within a defined range, this requirement should also be consistent in the HHS and DOT regulations. Another commenter stated that the purpose of blind performance testing is to determine a laboratory's ability to detect a substance and not to verify its ability to determine concentration levels. This commenter also noted that there are no standards for manufacturing blind specimens and that metabolites may adhere to the containers or leach out of the blind specimen, thus resulting in a lower concentration level of a metabolite being reported. Another commenter stated that licensees should not establish concentration ranges for blind specimens, but that, if a licensee's testing levels differ from the HHS levels, it may be appropriate to allow different concentrations in the positive blind specimens.

NRC response: The NRC has decided to adopt changes made to the HHS Mandatory Guidelines and establish specific criteria in section 2.8(e) of Appendix A. A specific concentration range (60 to 80 percent of screening cutoff values) is established for 10 percent of the positive blind specimens as a QA/QC measure of the laboratory's ability to determine specimen validity and perform special processing.

In response to inquiries concerning any technical difficulty in manufacturing spiked blind performance specimens within a defined range, leading toxicologists have assured the NRC that vendors that formulate blind specimens should be capable of providing diluted or adulterated specimens spiked to plus or minus 10 percent of any value, whether it is the normal cut-off level or 60 percent of that level.

NRC question 7(b): Should the NRC require that providers of performance test specimens be separate and independent (no conflict of interest) from those performing the specimen collection, specimen testing, MRO, and auditing functions?

Summary of comments: Three commenters did not agree that providers should be separate and independent. One commenter stated that, as long as quality control blind performance specimens are certified by immunoassay and gas chromatography/mass spectrometry (GC/MS) testing, the provider does not need to be separate and independent. This commenter also stated that current industry experience indicates that there is no need for further restrictions. However, if audits reveal compromises, this commenter thought that the HHS Mandatory Guidelines would be the appropriate vehicle for such restrictions. Another commenter stated that in the eight years of the HHS certification program there has not been a conflict of interest situation that has prevented a problem from being reported.

Three commenters agreed that test specimen providers should be separate and independent to avoid conflicts of interest. One of these commenters stated that it would ensure that the laboratory does not pre-record results in its reporting system.

NRC response: At this time the NRC will not require that performance test specimen providers be separate and independent from providers of other contracted laboratory services. The NRC will, however, continue to monitor HHS's development of policy in this regard.

NRC question 8: The NRC has received requests from several licensees and vendors to permit the onsite use of non-instrumented, qualitative immunoassay methods that involve the use of inexpensive, disposable devices. As discussed in more detail under the proposed changes to section 2.7 of Appendix A, these screening techniques have not been validated to achieve the high levels of specificity and accuracy that are needed in FFD programs. Of concern to the Commission is that these devices may produce an unacceptably high number of false negative test results and may be easily subverted.

NRC question 8(a): The Commission invited public comment on the advisability of creating guidelines, quality assurance procedures, and performance standards to govern use of these devices.

Summary of comments: Several commenters, responding to the NRC's concern about specificity, accuracy, and quality control procedures, pointed out the widespread acceptance of these devices in hospital laboratory environments. These commenters suggested that this acceptance shows that the devices are of equal or superior utility as compared to testing conducted in a laboratory setting. Otherwise, they would not be used so extensively in clinical settings which are regulated by the Clinical Laboratory Improvement Act (CLIA) proficiency and validation standards. Other commenters pointed out that all immunoassays are subject to subversion regardless of whether they are non-instrumented testing devices or laboratory tests. These commenters maintained that many of the existing controls for urine specimen collection and onsite drug testing already address techniques for prevention of subversion of testing using either instrumented or non-instrumented devices. In addition, it was pointed out that many non-instrumented testing devices have internal controls to detect adulteration of specimens which, while not universally effective, do provide additional defensive measures.

Several commenters noted that clinical testing of non-instrumented testing devices has been conducted and results published in professional journals. Two commenters provided results of studies measuring the specificity and accuracy of these devices. These studies appear to indicate that the devices yield results with regard to accuracy, specificity, and the number of false negatives that are comparable to instrumented testing devices. However, some uncertainty was expressed due to the dearth of validation studies conducted by objective evaluators who are not manufacturers of the devices. (Note: A study conducted for the Administrative Office of the U.S. Courts, and completed in early 1997, concluded that false negative results are still a problem for at least some of the devices.) Commenters requested guidance as to other sources of validation processes that might be considered suitable for validation of non-instrumented testing devices. One commenter pointed out that, in the absence of a particular Federal agency to perform formal validation studies, the historical practice of relying on third-parties to validate laboratory methods should also be sufficient to validate non-instrumented testing devices.

Other commenters supported developing industry-sponsored guidance regarding non-instrumented testing devices. The commenters suggested that the U.S. Food and Drug Administration (FDA), HHS, or the Nuclear Energy Institute could develop such guidance, or that joint guidance could be developed based on discussions between NRC staff and industry representatives. They also recommended that this guidance address NRC concerns about the testing devices and identify the most effective implementation methods with regard to developing controls to prevent subversion, confidentiality, and recordkeeping.

A number of commenters recommended specific quality assurance procedures and performance standards that could be followed if non-instrumented testing devices are authorized. These recommended procedures and standards included: (1) a requirement that the manufacturer's recommended quality assurance procedures be followed; (2) a requirement

that, upon the receipt of each lot of the product, a quality test would be conducted using certified positives and a certified negative for each drug on the panel; (3) a prohibition of the use of devices and materials that have past due expiration dates; and (4) the investigation of non-instrumented testing device errors and other matters accomplished in accordance with § 2.8 (f) of Appendix A to Part 26.

NRC response: The NRC has decided to prohibit the use of non-instrumented screening devices to test for drugs of abuse pending an expected HHS/SAMHSA decision as to whether these devices should be used in Federal workplace testing programs. HHS has been tasked by Congress to review the use of these devices. The Administrative Office of the U.S. Courts is also addressing the onsite use of non-instrumented testing devices and, as noted above, has recently completed an in-depth evaluation of these devices. At this time, it appears that false negative results are still a problem for at least some of these devices. The relevant comments submitted to the NRC on this issue have been forwarded to HHS. The NRC will permit the use of non-instrumented devices in tests to determine the validity of specimens.

NRC question 8(b): Alternatively, should the Commission prohibit the use of these devices until HHS (or another agency) has developed guidelines, procedures, and standards?

Summary of comments: Some commenters addressed this concern by pointing out that the rule's current requirement that testing devices meet U.S. Food and Drug Administration (FDA) standards addresses this issue, as the FDA reviews the devices for completeness and statistical validity. In addition, several commenters stated that many of the concerns raised by the NRC in the proposed rule are not specific to disposable non-instrumented qualitative immunoassay devices, but that they would apply to any currently used screening assay whether instrument based or non-instrument based. If the use of non-instrumented testing devices were authorized by the NRC, the devices would be subject to the same NRC inspection standards, licensee audit requirements, and blind sample testing, etc., as are instrumented immunoassay testing methods.

Another commenter suggested that, if use of onsite non-instrumented testing devices is to be prohibited pending independent validation, then independent evaluation should be applied universally to all testing methods, whether on site or at an HHS-certified laboratory. If this universal requirement is applied, then all testing methods, including those instrumented devices currently used, that have not undergone such a specific validation process should be prohibited until such independent validation is obtained.

One commenter agreed with the NRC's concern that the use of non-instrumented testing devices would probably result in a higher rate of false negative results and should not be included in the rule. Another commenter responded that currently there is not sufficient information available for the NRC to allow the use of non-instrumented testing devices for onsite tests. However, the majority of commenters expressed their support for non-instrumented testing devices and recommended that the NRC not prohibit the use of the devices. The commenters described the utility and advantages of onsite non-instrumented testing devices. Cited advantages included: 1) the immediacy of test results that, in the case of negative results, allows employees to quickly return to work and, in the case of positive results, minimizes denial of substance abuse because the tests are performed in the presence of the employee; 2) the safety benefits of being able to quickly identify high risk individuals; 3) the deterrent effect generated by the possibility of a random onsite test that yields immediate results; 4) cost savings due to reduced cost of the tests, immediacy of results, and the elimination of the need for an onsite laboratory; 5) better chain-of-custody procedures because fewer specimens have to be transferred to a testing facility; 6) the ability to use the tests

around the clock; 7) the ability for specimen donors to provide specimens on site rather than having to report to a nearby clinic or hospital; 8) quicker in-processing time of contract workers who have negative pre-access tests; and 9) the reduced skill levels required of testing personnel.

NRC response: Currently, it appears that false negative results for at least some of the non-instrumented screening devices are still a problem. Until HHS makes a ruling on the acceptability of these devices in workplace settings, the NRC will prohibit the use of non-instrumented testing devices.

NRC question 8(c): Should there be a Conforming Products List for these devices similar to that published by the National Highway Traffic Safety Administration (NHTSA) for evidential breath measurement devices? Who should administer such a program?

Summary of comments: Several commenters recommended that a Conforming Products List be developed for non-instrumented testing devices. One commenter recommended that this list include, and be applicable to, all test methods used in onsite laboratories or in HHS-certified laboratories. The commenter suggested that the Conforming Products List could be used as part of a validation program for all testing devices. Another commenter suggested that the FDA's approval of non-instrumented testing devices for commercial distribution precludes the need for a Conforming Products List. The commenter recommended that, if a Conforming Products List is required for public acceptance issues, administrative delays should be minimized as much as possible so that new devices are included on the lists as soon as they become available on the market.

NRC response: The NRC will await the HHS/SAMHSA ruling on the use of non-instrumented screening devices before addressing the issue of a Conforming Products List.

1. *Other Specific NRC Questions.*

In addition to the eight questions the NRC posed in the May 1996 Federal Register notice, the Commission also asked other questions in the general discussion section of that notice. These questions, a summary of comments received, and the NRC's responses are provided below.

NRC question: The NRC understands that some contractors have requested escorted access for individuals with a drug history without informing the licensee of that history. The NRC requested comments as to whether the rule should be revised to explicitly prohibit this practice.

Summary of comments: No comments were received in response to this question.

NRC response: Section 26.23 (a)(2) has been revised to make it clear that personnel who cannot be assigned to duties covered by Part 26 without the knowledge and consent of the licensee include those with a known history of substance abuse.

NRC question: The NRC requested data on the number of times that FFD programs have had to draw blood specimens in conjunction with alcohol testing and on any instance in which the use of blood alcohol concentration (BAC) results were overturned. The NRC also requested information on approaches licensees have taken to maintain the capability to draw blood for this purpose and on the associated costs.

Summary of comments: Several commenters provided data on the number of times they have drawn blood specimens to confirm positive breath alcohol tests. Four of the commenters cited no instances in which a positive breath alcohol test result was overturned due to contradicting blood test results. These four commenters recommended that the blood draw

requirement be eliminated because it is costly and not required under the DOT program. A fifth commenter maintained that the blood draw provision is useful because breathalyzer equipment occasionally may be unreliable, and because blood alcohol test results are more defensible in court than breath alcohol test results. This commenter cited two instances in which the result of a positive breath alcohol test was overturned due to negative blood alcohol test results. This commenter also noted two civil litigation cases in which blood alcohol test results provided increased defensibility for employment actions.

NRC response: The NRC has carefully evaluated the comments and determined that it is desirable to maintain the requirement that individuals have the option of providing a blood specimen for analysis to obtain additional information for appealing positive alcohol tests.

NRC question: Should the NRC develop a management information system similar to that promulgated by DOT and its operating administrations (December 23, 1993; 58 FR 68194 through 68285)?

Summary of comments: One commenter specifically recommended that the NRC not adopt the management information system promulgated by DOT for several reasons. Among the reasons cited were several additional reporting requirements and the differences between the DOT system's reporting format and the current NRC system's reporting format.

NRC response: At this time, the NRC will not be developing a management information system beyond the reporting requirements of §§ 26.71(d) and 26.73.

NRC question: The NRC requested comments on potential program performance indicators in addition to those contained in the proposed amendments to the rule and whether they should be added to the rule or included in a guidance document.

Summary of comments: One commenter suggested that the NRC follow the railroad industry and require reporting of sufficient information to establish the performance basis for a nuclear industry-wide random testing rate based on historical positive test result percentages. This commenter also recommended that, instead of the NRC adopting the proposed amendments to the reporting requirements, licensees should collect data as needed to support performance-based FFD programs.

NRC response: The NRC is exploring the potential utility, feasibility, and relative costs and benefits of FFD program performance indicators. Some of the potential uses being examined are the ability of performance indicators to help evaluate the FFD rule and its requirements, assess licensee programs, determine where to focus regulatory inspections, provide a basis for licensees to determine self-audit needs, and promote a more performance-based approach to FFD regulation. The NRC is addressing how different types of performance information can be best combined to create an effective and efficient approach to FFD program evaluation and regulation.

NRC question: The NRC requested comments regarding the proposed revisions concerning specimen degradation and whether rule changes should be made or the information published in report form for voluntary use. In particular, the NRC expressed interest in data that licensees conducting onsite testing could provide regarding onsite unconfirmed positives that had degraded during shipment. Licensees or other parties submitting this information were requested to include any known factors, such as temperature and duration of exposure to the suspect condition, that may have contributed to the problem.

Summary of comments: The NRC received no data in response to this request, although some licensees provided data during the development of the proposed amendments.

NRC response: The NRC wishes to thank those licensees that voluntarily provided data on this issue prior to publication of the proposed revisions, some of which was derived from informal experiments. As described in the May 1996 Federal Register notice at 61 FR 21122, data and reports from licensees supported NRC's pilot tests to gain insight into the nature and extent of the specimen degradation problem. The NRC anticipates no further action on this issue at this time beyond the revisions that have been adopted.

NRC question: The NRC sought public comment on the potential impact of the collection of information contained in the proposed rule. Comments were to be submitted by June 10, 1996, to the OMB on the following specific issues: 1) Is the proposed collection of information necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility? 2) Is the burden estimate associated with the information collection requirements correct? 3) Is there a way to enhance the quality, utility, and clarity of the information to be collected? and 4) How can the burden of the information collection be minimized, including the use of automated collection techniques?

Summary of comments: Several comments dealt with the rule revisions' potential impact on the information collection requirements. One commenter thought that the information that licensees submit in their semiannual Performance Data Reports is not necessary for the NRC to perform its Part 26 functions. This commenter maintained that the requirement that licensees report this information does not increase the assurance that personnel are not under the influence of any substance or mentally or physically impaired. The commenter also recommended that the reporting requirements be amended so that licensees would be required to report only information needed to support performance-based FFD programs. On the issue of the burden estimate associated with the information collection requirements, this commenter thought that the NRC had underestimated some of the increases in burdens that the rule changes would create. The commenter stated as an example, while a 15-minute estimate for a telephone call may be accurate, this estimate does not include at least one hour's worth of preparation time to compile and evaluate information about an event, inform management, and coordinate the call with licensing personnel. This commenter also recommended some ways in which, in his opinion, the quality of the information collected can be improved and the burden associated with information collection can be minimized. The commenter recommended that licensees be allowed to report information on an annual, rather than a semiannual, basis; that utilities be given the option to submit either individual site reports or one consolidated report; and that contractor/vendor personnel be reported as only one category rather than as long-term or short-term workers. This commenter also suggested that the NRC establish an electronic mail system for the industry to use to submit necessary information.

NRC response: The NRC continues to believe that the program performance information that licensees routinely collect and report to the Commission is both necessary and useful. The NRC requires program performance data for its evaluation of the ongoing effectiveness of the program and to identify program weaknesses. The analysis provided in the annual program performance summary report is intended to enable the NRC and its licensees to evaluate any individual FFD program relative to industry-wide program performance. In addition, many licensees include lessons learned, which have been included in the annual reports. Some licensees have indicated that they find their reports and the NRC's annual summary report to be useful for these purposes. Therefore, the NRC concludes that the report is useful when used as intended.

In reference to the suggestion that the NRC collect only information required to support performance-based FFD programs, the NRC concurs that routine data collection and analysis is

the heart of any performance-based program. Increased emphasis on performance-focused programs will increase the need for additional routine ongoing collection of the types of data discussed in the NRC's May 1996 Federal Register notice. Having access to this information would enable the NRC to gain a clearer and more detailed understanding of the actual operation of the programs. It would be infeasible to examine the subject data during NRC inspections because the NRC conducts for-cause inspections rather than routine inspections of licensee's FFD programs. The NRC is continuing to consider the desirability of collecting additional data for these purposes.

Insofar as the potential for underestimation of some burden increases associated with reporting requirements is concerned, the NRC did include some time for internal coordination when estimating these costs. The NRC may not, however, have included sufficient time for all the internal coordination or documentation as described by the commenter. Therefore, an adjustment to the burden estimate for internal coordination has been increased from 15 minutes to 30 minutes.

The NRC concurs that reporting of program performance data should be on an annual or semiannual basis and has revised the reporting requirements of § 26.71(d) accordingly. However, the NRC declines to permit consolidated reporting by utility. The NRC uses information reported from each site for a number of purposes. In addition to being used to produce the annual summary report, data from program performance reports are used to compare site performance with industry averages, to track each site's performance over time, to note unusual performance over time at each site, and to identify site specific issues for follow up. These various purposes preclude the reporting of results at the utility level.

With regard to the reporting of data for long- and short-term contractors and vendors, the rule currently does not specifically require separate reporting of test results for long-term and short-term contractors. The NRC will be discussing with NEI changes to the program performance reporting form, which NEI developed, to address changes required by the revisions to the rule. These discussions will include whether long- and short-term contractors' test results should continue to be reported separately.

Finally, the NRC has undertaken the task of initiating a rulemaking that will give licensees, applicants, and other entities the option to submit documents electronically to the NRC. The rulemaking, which will also provide the procedures for making electronic submittals, will facilitate the capture of documents into the Agencywide Documents Access and Management System which will become operational during FY2000. In addition, the NRC has no objection to NEI or another industry group creating an electronic mail system acceptable to the NRC for submitting information when the data collection format is revised in response to the FFD rule revisions. The NRC will continue to capitalize on information technology for improving information access, information distribution, and public interaction. However, the NRC will not eliminate paper in favor of electronic communication without full consideration of the public's ability to access information electronically.

2. *Comments About Including FFD Program Personnel Within the Scope of Part 26.*

Several commenters took exception to subjecting some FFD program personnel to Part 26 requirements. Some commenters suggested, for example, that employee assistance program personnel and/or MROs should not be covered by Part 26 because they do not have access to the areas or materials described in § 26.2(a) and many are offsite contract employees. Others argued that the rule should be applicable only to those FFD personnel who make decisions regarding testing. Questions about who will test the FFD program staff were also raised.

NRC response: The NRC has revised § 26.2 to clarify its original intent that the specified classes of personnel who administer FFD programs must be covered by Part 26 even though they may work outside the plant protected area. The NRC continues to believe, and industry experience indicates, that FFD program personnel must meet the highest standards of honesty, integrity, reliability, and trustworthiness. While some of these people may not work in protected areas, they do make important decisions regarding the testing of employees who have access to protected areas and perform duties with direct implications for public health and safety. FFD programs must be able to ensure that program personnel do not make errors of omission or commission that can jeopardize program integrity and effectiveness. To clearly identify those individuals whose FFD program responsibilities require that they be tested, the NRC has modified the changes to § 26.2 as proposed (i) to limit the applicability of the linking of test results to those FFD program personnel who can link test results with the person who was tested prior to determination of a FFD policy violation, (ii) to eliminate those making removal and return-to-work recommendations as opposed to decisions, and (iii) to add those making medical and management determinations of fitness.

The NRC recognizes that the requirement that FFD program personnel shall be tested to the extent practicable by people who are independent of the administration of the FFD program may be difficult to meet in some instances. The NRC does not expect licensees to take impractical measures and a reasonable approach is sufficient to comply with this requirement.

The NRC also notes that it is still considering the proper scope of the rule following its 1994 request for information on whether certain categories of workers, such as secretaries, should be excluded from random testing. That issue is being addressed independent of this rulemaking.

3. *Comments About the Relationship to Other Federal Programs.*

Several commenters addressed the relationship of the NRC's FFD program to the employee drug testing programs of other Federal agencies. In general, commenters appreciated the NRC's attempt to create consistency between its FFD program and those of other agencies. However, several commenters raised the point that several differences still exist. Commenters were concerned about differences between the technical aspects of drug testing such as different cut-off levels, different procedures for reporting laboratory results, and different alcohol testing processes. Differences in overall program philosophy, goals, and mandates were also areas of concern to commenters. In particular, some commenters thought that the Commission's new § 26.2(f) would be difficult to interpret and ineffective in reducing unnecessary duplication between the NRC and other agencies' FFD requirements.

NRC response: The NRC desires to provide as much relief as possible, without jeopardizing public health and safety, for licensee, contractor, and vendor employees who are covered by multiple Federal workplace drug testing programs. However, given the NRC's explicit responsibility to ensure public health and safety within the commercial nuclear industry and NRC's conclusion that some differences are necessary (as described below), complete correspondence with other Federal programs is not appropriate.

The NRC has revised § 26.2(f) to provide licensees with more direction in reducing unnecessary duplication between the NRC and other agencies' FFD requirements. The reference to "general performance objectives" in the new section as originally proposed has been replaced with more specific language. Licensees must still ensure that all people performing activities under Part 26 are covered by all program elements described in §§ 26.20 to 26.73. These program elements can be provided either by the licensee's Part 26 program,

by another Federal agency or State program, or combination thereof, as long as certain key elements meet NRC program standards.

4. *Comments About HHS Changes and Related Issues.*

A number of commenters responded to the request for comments regarding whether the NRC should incorporate revisions HHS made to its Mandatory Guidelines in June 1994. In general, commenters supported consistency with the HHS Mandatory Guidelines with adjustments to those guidelines to respond to the specific safety requirements of the nuclear industry. However, some commenters supported complete consistency with the HHS Mandatory Guidelines, including incorporating those guidelines by reference and making acceptance of new or revised HHS Mandatory Guidelines automatic.

NRC response: The NRC concurs with the commenter's view of the value of a general acceptance of the HHS Mandatory Guidelines revisions, and the need to make adjustments to some of those revisions to respond to the nuclear industry's specific needs. The NRC believes that consistency across Federal programs is desirable when practicable. However, as described below, the NRC concludes that some program differences are necessary. While much of the HHS Mandatory Guidelines has been adopted as published by HHS, the NRC has made some modifications to achieve compatibility with the NRC's responsibilities for assuring public health and safety. Adoption of a procedure that would automatically incorporate HHS Guideline changes would not allow the consideration of issues specific to the nuclear industry.

In adopting changes to the HHS Guidelines published in the Federal Register on June 9, 1994 (59 FR 29908), and September 30, 1997 (62 FR 51118) some of the HHS changes will be modified to address an NRC need, as follows:

A. Change to HHS Guidelines: Reduce the required minimum quantity of each urine specimen from 60 ml to at least 30 ml. An additional 15 ml is required when split specimens are collected.

NRC modification: Because additional urine would be needed for onsite testing and testing for additional drugs, the NRC will require that the total volume collected must be predetermined by each licensee to meet its unique needs.

B. Change to HHS Guidelines: Reduce the maximum number and percentage of blind performance specimens to be submitted per quarter.

NRC modification: Because several licensees conduct onsite testing and, therefore, submit a significantly lower number of specimens to the HHS-certified laboratory for further testing, the NRC will require a minimum of 30 samples during the initial 90-day period and 10 per quarter thereafter to provide adequate quality assurance. Also, the NRC will require a maximum number of specimens that are less than those adopted by HHS (100/25 by NRC instead of 200/100 by HHS).

C. Change to HHS Guidelines: Clarify that laboratories may determine the validity of a specimen (to determine if the specimen is adulterated or diluted). This has been supplemented by NLCP Program Document #35 which directs the HHS-certified laboratories to determine specimen validity through tests for creatinine, specific gravity, pH and nitrites.

NRC modification: Because attempts to subvert the testing process is regarded by many authorities as the most serious threat to the efficacy of FFD programs being confronted today, the NRC will require that the validity of all specimens be determined to prevent or detect attempts to avoid detection through adulteration or dilution of specimens consistent with NLCP Program Directive #35. This would supplement other measures specified in Part 26, such as a time limit between notification and collection and using a more restrictive temperature range. Most laboratories have indicated that determining specimen validity would be a "normal cost of

doing business" and no cost would be passed on to the licensee. One laboratory has indicated it would probably increase the cost of testing by approximately \$1 per specimen.

D. Change to HHS Guidelines: Permit multiple immunoassay (screening) tests for the same drug or drug class.

NRC modification: Because the language in the HHS Guidelines could be interpreted as endorsing multiple screening tests for all drugs as a routine practice (which would increase the number of false negative testing results) and because HHS staff emphasized that this procedure should only be applied to amphetamines (where structural analogues cause specificity problems) and special circumstances where valid results cannot be obtained, the NRC will adopt clarifying language, which was provided by HHS.

E. Change to HHS Guidelines: Require that the MRO review and report to management in writing all test results, both positive and negative, and in a manner designed to ensure confidentiality of the information.

NRC modification: HHS adopted this change to ensure that all specimens have been tested and the results of all specimen tests have been reviewed by the MRO. The NRC believes that the objectives of the HHS requirements can be achieved at no cost by codifying current general practice. Therefore, the NRC will require licensees to have a procedure to ensure all collected specimens have been tested and that all MRO determinations of positive test results and attempts to avoid detection are reported to licensee management in writing. That report to management can be accomplished by use of the Federal Drug Testing Custody and Control Form, or "look alike," which the laboratories are required to use. Copy 7 is specifically intended to be sent to management.

F. Change to HHS Guidelines: Specify detailed collection and dispatch procedures for split specimens.

NRC modification: The NRC staff regards the current provisions to be adequate, except for minor clarifications. Therefore, the level of detail contained in the HHS Guidelines is not necessary.

G. Change to HHS Guidelines: Establish a 72-hour time limit within which an individual must request testing of the split specimen.

NRC modification: Because the current rule does not set a time limit for requesting a test of a split specimen, but does require a retest of the original specimen in response to a "timely request," the NRC is establishing a consistent timeliness standard for both tests.

Also, because licensees need flexibility to determine appropriate time limits without imposing an unreasonable burden on the individual, the NRC will permit licensees to set a timeliness standard, but not less than 72 hours.

H. Change to HHS Guidelines: Raise the screening test cutoff level for opiates from 300 to 2,000 ng/ml (deleting the requirement for 25 ng/ml to be specific for free morphine) and raising the confirmatory test cutoff levels for morphine and for codeine from 300 to 2,000 ng/ml. A new requirement is added to establish a cutoff level for 6-acetylmorphine (6-AM) at 10 ng/ml when the morphine concentration exceeds 2,000 ng/ml.

NRC modification: The NRC requested specific comments on this anticipated change. The majority of commenters disagreed with raising the opiate screening and confirmatory levels, citing the high level of concern for safety in the nuclear industry. Based on the safety considerations presented by the commenters, the NRC will maintain current cutoff levels for opiates at this time. To eliminate unnecessary confirmatory tests, the NRC will adopt the HHS policy with respect to testing for 6-AM. Testing for 6-AM will be required only when confirmed morphine concentrations exceeds 2,000 ng/ml.

5. *Comments About “Medical Determination of Fitness” and Other Definitions.*

The proposed definition of “medical determination of fitness” elicited a number of suggestions and questions from commenters. Some commenters questioned the need for a medical determination of fitness or management determinations of fitness. One commenter noted a potential conflict between the requirement that MROs or other licensed physicians make fitness determinations and other rule language that requires such determinations to be made by designated licensee representatives. A number of commenters dealt specifically with the MRO’s role in these determinations. One concern was that this definition makes MROs explicitly responsible for a number of administrative and management decisions. Some commenters thought that the increased responsibilities of the MRO position might prove burdensome and create availability issues. Others suggested that this definition be revised to permit health care professionals other than licensed physicians to determine workers’ fitness when that fitness is questioned.

Some commenters recommended that the final rule allow health care professionals other than licensed physicians/MROs to be used to determine fitness. They contended that the proposed definition would require licensees to employ full-time physicians and that the requirement that MROs make medical determination of fitness in the five categories stated in § 2.9 (g)(1) of Appendix A would be burdensome for licensees.

Several comments were received regarding other proposed and revised definitions in § 26.3. Some of the commenters recommended revisions that involved the inclusion of procedural and policy guidance.

NRC response: The NRC continues to believe that considerations of safety dictate that both licensed physicians and appropriate management personnel jointly share the responsibility of determining whether employees are fit to resume Part 26 activities. However, after consideration of the public comments, the Commission has decided not to adopt the requirement that a medical determination of fitness be performed to evaluate employees who test negative in a for-cause test. In situations such as preaccess and return-to-duty testing, the fitness determination is ordinarily made during normal work hours when the MRO is on-duty. By contrast, the need for a medical determination after a negative for-cause test could occur during off-normal work hours when the MRO is not available. In this situation, the licensee would have the following options: (1) provide an MRO on a 24-hour or as-needed basis or (2) defer the medical determination until normal work hours. The added costs and reduced flexibility would only occur in negative for-cause tests, and there is insufficient data to show that such costs would be justified in terms of the identification of significant numbers of unfit workers would only be identified as unfit by the MRO. Therefore, the Commission has decided that a medical determination after a negative for-cause test is not warranted.

The Commission has defined “medical determination of fitness” to clarify the MRO’s, or other licensed physician’s, role in determining fitness for duty and to provide a standard for what constitutes this determination.” Considerations of safety and program integrity also require that licensed physicians, rather than other types of medical personnel, continue to make these determinations. Therefore, medical determinations of fitness must be performed by a qualified licensed physician, who may be an MRO. The NRC sees no conflict between the definition of “medical determination of fitness” in § 26.3 and the requirement that fitness determinations be made by an appropriate manager and a licensed physician in § 26.27(b). Only the physician is required to be qualified in the factors to be considered as described in the definition of a “medical determination of fitness.” The definition’s statement of the elements of what constitutes a medical determination of fitness presents no new concepts

and does not change the MRO's relevant duties. MROs have always been responsible for understanding the administrative and management areas relevant to their duties.

With respect to the availability of a qualified physician, the NRC does not believe that the requirements suggest the need for a full-time physician. The medical determination of fitness must be a careful evaluation of all relevant data and should not be a superficial effort whose whole purpose is to return the individual to duty before replacement personnel are called in. It is because some licensees have quickly returned workers to duty without an adequate determination of fitness that the NRC decided to clarify the rule.

The NRC believes that procedural and policy guidance is more appropriately provided and adequately specified in other sections of the rule or in Appendix A to Part 26 and need not be addressed in the § 26.3 definitions.

6. *Comments About Pre-access Testing.*

Several commenters raised issues regarding the proposed revisions to the § 26.24(a)(1) pre-access testing requirements. The majority of comments concerned the in-processing procedures that would be required to implement efficiencies that would be allowed for both new and returning employees under the revised rule. Some commenters thought that management and tracking requirements would be too complex and might lead to inadvertent non-compliance when large numbers of workers are processed, for example, during outages. Commenters also focused on the pre-access testing procedures for workers who previously had been covered by a program meeting Part 26 requirements. These commenters suggested that an employee who has been appropriately covered within 60 days prior to the granting of unescorted access, instead of the proposed at least 30 days during the previous 60 days, be excused from the requirement of pre-access testing. Some commenters requested that the Commission grant greater flexibility and that the period within which previous coverage under a FFD program would negate the need to conduct a pre-access test be extended to a full year. One commenter, for example, recommended that only one day of FFD program coverage out of the previous 365 days should be sufficient to eliminate the need for a pre-access test. Several commenters believed that unescorted access should be granted to all applicants who have had a negative breath alcohol test and whose drug tests were pending.

NRC response: The NRC has decided to retain the proposed increased flexibility in the pre-access testing requirements. These revisions should produce FFD program efficiencies because some unnecessary pre-access testing will be eliminated and some employees who have demonstrated reliability will be able to gain immediate access rather than having to wait for negative test results. If licensees are unable to take full advantage of these efficiencies at this time because the industry's personnel access data base does not contain the necessary information, licensees can continue to conduct pre-access testing using the same procedures they have used in the past. With respect to commenters' requests for greater flexibility in granting access to employees who have previously been covered by a program meeting Part 26 requirements, the adopted revisions to § 26.24(a)(1) reflect the maximum degree of flexibility and departure from previous pre-access testing requirements that the Commission deems to be reasonable and prudent.

7. *Comments About Random Testing.*

The proposed revisions intended to clarify the random testing requirements of § 26.24(a)(2) generated many comments. Some commenters requested specific guidance and clarification on implementation of the random selection procedures. Many commenters specifically raised the issue of how random testing procedures should be conducted with regard

to infrequent and irregular site workers such as contractors or corporate employees. Several commenters suggested that the proposed revisions would create an unnecessary burden for licensees. These commenters interpreted the requirement that workers who are off site at the time of selection be tested "upon returning to the site" as potentially requiring that FFD staff have a constant presence on site.

The NRC's proposed rule revisions did not include any proposed change to the random testing rate. Nonetheless, one commenter stated that the industry intends to develop a proposal to shift the random testing rate from 50 percent of the population to a performance-based regime based on historical positive test result percentages. The commenter also noted that the industry also intended to support data collection to provide the basis for this proposal.

NRC response: The NRC is clarifying the random testing requirements to more fully describe the random testing selection process for licensees that may be administering the process incorrectly. These practices compromise the randomness of the testing process. The NRC has clarified the random testing requirements in response to cases of random testing practices that involve simply returning the names of the individuals who are selected for testing but not on site to the "pool" and testing those who are available. This practice subjects those individuals who are routinely on site to random testing at a higher frequency than those who are not routinely on site. This issue was addressed clearly in responses to comments on the original proposed rule (see NUREG-1354) and in NUREG-1385 which responds to implementation questions. The practice of returning employees' names to the testing pool without testing is not consistent with the requirement that all persons in the testing pool have an equal probability of being selected and actually being tested. The NRC declines to distinguish between licensee employees and contractors with regard to this aspect of random testing.

The NRC intends that all personnel shall have an equal likelihood of being randomly selected for testing and of being tested when selected. To assure this, testing periods must include all shifts. Also, it is not the NRC's intent that licensees' specimen collection facilities be attended 24 hours a day or that collection personnel be routinely called in to administer random tests during off shifts. In many cases, there will be an "overlap" at the beginning or end of a shift when the selected employee and the collector are both available for the test. If a worker is not on site at the time of selection, the worker is to be tested, without prior notification, when he or she returns to the site, or at the earliest convenient opportunity. To make this flexibility clear, the phrase "at the earliest reasonable and practical opportunity" has been added to § 26.24(a)(2). "Reasonable and practical" mean that a licensee's notification and collection procedures should use common sense and achieve the desired purpose in an efficient manner. Developing more specific regulatory language to cover all possible situations would be difficult; however, some examples are described below.

A person not available for testing could be "added" to successive groups of persons selected for testing until that person is actually tested. Licensees may maintain separate selection pools for any class or group of workers, such as corporate personnel, but are not to discriminate within that pool. Corporate workers who have been randomly selected must also be tested as soon as practicable. Licensees may choose to have these workers report to the site (which may compromise the desired brief interval between notification and testing), have the specimen collected at the corporate headquarters (several days of selections can be combined for efficiency as long as prior notification standards are met), or test the individual the next time on site (after considering the "reasonably available" standard for random testing set forth in the rule). Licensees that do not maintain permanent collection facilities and collection personnel at their corporate headquarters may establish temporary collection facilities and send medical staff from the site on occasion to collect specimens or use trained non-medical persons

to collect specimens, as permitted by section 2.2(d)(2) of Appendix A. Licensees should also be aware that NUREGs-1385 and 1354 discuss acceptable techniques for random selection and testing.

In response to the comment regarding a possible industry initiative to propose a performance-based alternative to the current 50 percent random testing rate, the NRC notes that it continues to believe that using positive random test results as a performance-based measure to determine random test rates is inappropriate. A low positive test result rate may represent either an effective program that is deterring substance abuse or a program that fails to effectively detect drug and alcohol abuse.

8. *Comments About For-Cause Testing.*

Commenters disagreed with the proposed revision to § 26.24(a)(3) that specified attempts to subvert the testing process as one type of event that would require for-cause testing. Commenters thought that this explicit requirement could compromise licensees' ability to deny unescorted access when they detect subversion in cases when the for-cause test result is negative or shows no signs of adulteration or dilution. Commenters also raised other concerns regarding revisions that would specify time limits for obtaining for-cause samples. They warned that operational considerations might delay the testing process and that due process and sufficient review could be compromised in the effort to comply with the proposed time requirement.

NRC response: The NRC agrees that the proposed revision to § 26.24(a)(3) could potentially have limited licensees' authority to deny unescorted access based on subversion in cases where the for-cause test result is negative or shows no sign of adulteration or dilution. This section has been revised with the intent to allow the MRO and/or licensee management the discretion to determine whether a for-cause test is appropriate after detecting subversion attempts. With respect to time limits for conducting for-cause testing, it is the NRC's intent to provide a reasonable relaxation of the current "as soon as possible" standard and ensure licensees conduct for-cause tests before workers have a chance to "flush" their systems or metabolize the substance to below the concentration levels specified in the rule. Section 26.24(a)(3) will, therefore, require that for-cause tests be administered within the time limits as proposed. In response to commenters' concerns, however, the NRC has incorporated flexibility into this section by requiring the time limits to be observed "except under documented unusual circumstances."

9. *Comments About Return-to-Duty Policies.*

Several comments were received regarding the proposed return-to-duty requirements which consolidated and clarified requirements promulgated in the original rule. Commenters requested clarification of the requirement that licensees conduct a medical determination of fitness before returning employees to duty after a for-cause test. Some commenters objected to the policy that personnel who have been denied unescorted access for being impaired and in violation of the licensee's FFD policy must be determined fit to perform activities by an appropriate manager and licensed physician before being allowed to return to duty.

NRC response: Because there have been several instances in which licensees have "automatically" returned workers to duty without a determination of fitness, the NRC believes its expectations need to be clarified on this issue. The NRC believes that an adequate determination of fitness is necessary to protect public health and safety and is, therefore, a key element in the FFD program. The NRC is setting the standard to be used by licensees in § 26.27(b)(1) that no individual determined to be impaired, whose fitness may be questionable,

or who is in violation of a licensee FFD policy shall return to duty until determined to be fit for duty by an appropriate manager and a licensed physician qualified to make the medical determination of fitness.

In response to the comments regarding § 26.24(a)(3) return-to-duty requirements associated with for-cause testing, the NRC stresses, as it has in the past, that it is essential that employees who have been removed because of questionable fitness, or were subject to for-cause testing, be thoroughly evaluated for fitness prior to returning to duty. Licensees must conduct this fitness evaluation regardless of the event or condition that triggered the removal or for-cause testing. The for-cause test is only one part of that process. The event or condition must be thoroughly reviewed by appropriate medical and management personnel. The people making return-to-duty decisions must be aware that a negative test result does not assure that an employee can safely and competently perform his or her duties. There are other factors, such as fatigue, stress, or illness, that may cause the worker to be unfit to return to work. All of these factors must be evaluated.

10. *Comments About Follow-Up Testing.*

Some commenters took exception to the duration of the follow-up testing requirements specified in the rule arguing that they restrict the MRO's ability to tailor follow-up testing procedures to individual worker needs. In particular, commenters suggested that follow-up testing be required for only 1 year after return to duty and that the MRO be given the discretion to determine the number and frequency of these tests and any other follow-up tests that extend beyond the 1 year period.

Many commenters requested clarification of the circumstances under which follow-up testing is required. Issues raised by commenters included follow-up testing requirements for instances of prescription or over-the-counter (OTC) drug abuse, whether follow-up tests are required for violations that do not involve drug or alcohol use or in cases of self referral to an EAP, whether testing at the HHS-certified laboratory's limit of detection can be used for follow-up tests, and the possibility that a second positive drug test result might be the result of the drug use indicated by the first positive test result.

NRC response: Although follow-up testing has always been required, § 26.24(a)(4) has been revised to clarify how this requirement applies after a first positive test result. Based on a review of the technical literature and consultation with recognized experts, the NRC has determined that the 36-month period is the minimum required to assure continued abstinence. The NRC anticipates that the MRO will use the flexibility provided in the rule to establish follow-up testing requirements that are more frequent or of a greater duration than the minimum specified in the rule, if deemed appropriate.

While the NRC does not require follow-up testing for FFD policy violations that do not involve or derive from drug or alcohol use, the rule provides flexibility so that such testing may be conducted when deemed appropriate (for example, when evaluation of self referral to the EAP indicates that substance abuse may be a problem). Nor does the NRC specify sanctions regarding people who are removed from duty as potential hazards to public health and safety for actions or conditions not related to drugs or alcohol. The NRC expects that EAPs and licensees will establish appropriate follow-up, monitoring, and return-to-work decisions for self referrals and for workers with questionable fitness resulting from issues other than drugs and alcohol. EAPs and licensees are allowed considerable flexibility in the way they handle these situations and are expected to use prudent judgment to assure public health and safety. The rule also provides the flexibility to use limit-of-detection testing in follow-up testing, although the NRC declines to make this a requirement for all such tests.

The NRC also recognizes that in rare circumstances a second positive test result is possible when successive collections are relatively close together, even when the person has not used the drug in question after providing the first specimen. In these cases, the MRO may determine that the second positive test result is due to the continued presence of the drug from the originally detected use rather than additional use. In these cases, the MRO can decline to find that a second FFD policy violation has occurred.

11. *Comments About Called-In Workers' Statements of Fitness.*

Commenters objected to the revision that would require employees who are called in for unscheduled working tours to state when they are contacted whether they consider themselves fit to perform the tasks assigned. Some commenters thought that this requirement would imply that employees routinely fail to maintain fitness when off duty. Others argued that this revision would enable employees to claim fitness issues and then refuse to perform undesirable tasks. One commenter inquired whether the NRC intended that employees who have consumed any alcohol should be required to stay at home.

NRC response: The NRC believes that most workers will appropriately respond in these circumstances as to their current fitness to perform their duties in a safe and competent manner. When employees are not scheduled for work nor are on call, they are not expected to restrict their activities such that they will always be immediately fit for duty. In cases where called-in employees consider themselves not fit to safely and competently perform their work because they have consumed alcohol or for other reasons such as fatigue or illness, the NRC believes they should not be required to travel to the work site. This would be in the interests of their own personal safety as well as the safety of plant operations. It would also eliminate the delay involved in replacing a person when it is determined that he or she is not fit after arriving at the site. However, since these are business decisions beyond the scope of the NRC's authority, the phrase "when contacted" has been removed from § 26.20(e)(1).

12. *Comments About Specimen Shipments and Deterioration.*

Some commenters objected to the requirement that there be a tracking system that identifies the courier company conveying the specimens to the laboratory because it would be unnecessarily burdensome and overly prescriptive and reduce the flexibility that licensees have in accomplishing chain-of-custody requirements. Other commenters disagreed with the proposed rule change to § 2.4(d) of Appendix A and recommended that the chain-of-custody (now custody-and-control) form should be signed by all handlers of the samples as has always been required.

One commenter recommended that the revisions regarding assurances that specimens are either chilled or transported to the laboratory be deleted and replaced with an advisory regarding specimen deterioration. The commenter argued that the detailed requirements would be difficult to monitor because many of the actors in the process do not come under licensee control. Another commenter recommended that the wording be simplified and the requirements made more flexible to make this section less confusing. Another commenter noted that the requirements that specimens be received at laboratories within 48 hours and screened within 72 hours would not be achievable over holiday weekends. The commenter recommended deleting this requirement.

NRC response: As noted in the Discussion section of the May 9, 1996, Federal Register notice, standard practice acceptable for forensic purposes is to have the courier company sign for and track the package of specimens rather than to sign the custody-and-control form for

each individual specimen. This practice is well established and follows the guidelines established by HHS, DOT, and the U.S. Department of Justice (DOJ).

Section 2.4(d) of Appendix A has been revised to make it clear that couriers do not have to sign the individual custody-and-control forms. This change reflects lessons learned by HHS, DOT, and DOJ about specimen custody requirements in response to a court case. Courier companies used by licensees routinely provide a tracking system that will assure custody accountability during shipment.

To continue to achieve the goal of preventing the deterioration of specimens while providing more flexibility, the NRC has revised § 2.4(i) of Appendix A to require licensees to ship specimens as soon as reasonably possible or to take reasonable and prudent measures to assure that specimen deterioration does not occur. The requirement for receipt of the specimen at the laboratory within 48 hours of shipment and screening testing within 72 hours of shipment remains with flexibility provided for unusual circumstances.

13. *Comments About Suitable Inquiries.*

Several commenters asked the Commission to modify the FFD rule's suitable inquiry requirement to be consistent with the temporary unescorted access provision of the access authorization program under 10 CFR 73.56. Two commenters recommended that licensees be authorized to grant temporary unescorted access when they have completed a suitable inquiry into applicants' activities over the past year, or have documented their best efforts to do so. Two other commenters recommended that licensees be authorized to grant temporary unescorted access upon initiation, as opposed to completion, of checks into applicants' employers over the past year. Still another commenter recommended that licensees be allowed to grant permanent unescorted access upon initiation, rather than completion, of the full five-year suitable inquiry.

One commenter supported the revision that would allow a suitable inquiry to not be conducted when employees have been away from coverage of an FFD program for 30 days or less. One commenter asked whether employees' answers to suitable inquiry questions indicating no prior drug involvement would be sufficient for proof of no history of substance abuse that would allow employees to forgo pre-access tests.

NRC response: The access authorization requirements set forth in 10 CFR 73.56 and Regulatory Guide 5.66 (which all licensees have committed to implement) currently requires licensees to complete a one-year employment check, among other things, before they can grant temporary unescorted access. The NRC agrees that the FFD rule should provide for the granting of temporary unescorted access consistent with the access authorization requirements. Section 26.27(a) has, therefore, been revised to authorize licensees to grant temporary unescorted access when they have received and evaluated the past year's suitable inquiry results, or documented their best efforts to do so, initiated the balance of the five-year inquiry, and the applicant has received a negative result on a pre-access test. The NRC disagrees strongly with the implication contained in some of the comments that not even a modest effort to determine suitability is needed before granting access. Any licensee allowing unescorted access based solely on the initiation of a suitable inquiry would be in violation of § 26.27 as well as commitments to implement 10 CFR 73.56 by following Regulatory Guide 5.66.

The NRC stresses that licensees are to verify the accuracy of all employee answers to statements related to the history of substance abuse and to other answers to suitable inquiry questions. Accepting at face value employees' statements that they have no prior history of substance abuse is not acceptable. It should also be noted that such a "history" goes beyond positive drug tests. It must include, for example, instances of subversion and refusals to test.

Also, a lack of a history of substance abuse is not a reason to allow an applicant for access to forgo pre-access testing.

Based upon information obtained after publication of the proposed rule, the NRC has decided to withdraw the provision that would no longer require licensees to conduct a suitable inquiry for instances in which an applicant was not covered by an FFD program for periods of employment of 30 days or less. Licensee FFD personnel have indicated to the NRC that adverse FFD information is frequently obtained through checks of employment of 30 days or less. In those cases, employment was terminated for cause (oftentimes for substance abuse) before 30 days. Licensee FFD personnel also pointed out that under the proposed rule, employees could conceal their FFD problems by ensuring that their employment at any one site is less than 30 days, thereby avoiding both FFD testing as well as minimizing the possibility that a subsequent licensee would discover any previous for-cause termination occurring within the thirty-day period of previous employment. Furthermore, based upon the comments of the FFD personnel, the NRC now believes that there may be a concern with the employee who moves from one job to another after being terminated repeatedly for cause prior to 30 days. For these reasons, the NRC believes that a relaxation from the current requirement of conducting a suitable inquiry for all periods of employment would increase the risk to public health and safety. Accordingly, the NRC withdraws the proposed rule's provision allowing a licensee to skip a suitable inquiry for periods of employment of 30 days or less. This will avoid a situation in which workers have gaps in employment/unemployment during which employer knowledge regarding behavior affecting trustworthiness and reliability may be effectively concealed or otherwise not detected by the licensee's program. The NRC notes that the current requirement for a suitable inquiry does not apply to current employees who are temporarily away from the site and therefore not subject to a FFD program; instead the return-to-work provisions in the final rule in Section 26.27 apply to those employees who have not been subject to the licensee's FFD program for a period greater than 60 days. Finally, the NRC recognizes that obtaining information from short-term employers has sometimes proven difficult, especially when such employment is outside the nuclear power industry. The current wording of § 26.27 that requires licensees to complete suitable inquiries "on a best-efforts basis" provides licensees with sufficient flexibility when obtaining such information becomes too burdensome.

14. *Comments About Blind Performance Test Specimen Requirements.*

The NRC received several comments regarding the proposed requirement that 10 percent of the positive blind performance test specimens that licensees are to submit to their HHS-certified laboratories be adulterated or diluted and spiked to 60 percent of the cut-off levels of the drugs for which the licensees are testing. Many commenters objected to the NRC's proposal to define the concentration for spiked performance specimens to confirm HHS-certified laboratories' capacity to determine specimen validity. They cited technical, implementation, and enforcement problems such as how to determine the exact concentration of a dilute specimen and the lack of standard manufacturing criteria. Some commenters also maintained that the NRC should not impose more stringent blind performance testing requirements than those imposed by HHS. Other commenters supported the proposed policy but emphasized the need for guidance in the specification of analyte concentrations.

NRC response: The NRC disagrees that the technical requirements for spiking specimens at 60 percent of the cut-off levels after diluting them would be difficult to implement and enforce. Vendors that formulate blind specimens should be able to provide diluted or adulterated specimens spiked to plus or minus 10 percent of any cut-off level. Assuring the validity and reliability of the testing process, including determinations of testing validity, must be

based, in part, upon the processing of blind performance test specimens. Leading toxicologists have stated that they have not encountered any problems in the preparation of such specimens.

The Commission has, however, decided to modify its originally proposed revision to the blind performance specimen requirements in § 2.8(e)(3) of Appendix A to permit licensees flexibility in the provision of adequate quality controls needed to support § 2.7(e). Section 2.7(e) will require licensees to have their HHS-certified laboratories screen test specimens of questionable validity at the lowest concentration level for which FDA-approved analytical kits are available. To accommodate this change, § 2.8(e)(3) has been revised to require that adulterated or diluted blind performance test specimens be spiked to between 60 and 80 percent of the licensee's cut-off levels.

15. *Comments About Combining Specimens of Insufficient Volume.*

A number of commenters objected to the rule continuing to authorize licensees to combine partial urine specimens to get the volume needed for testing. They noted that this practice is inappropriate when one of the specimens, usually the first one, is suspected of being adulterated or diluted. The commenters also pointed out that combining partial specimens tends to lower the concentration of any drug that may be present and that this practice is inconsistent with the HHS Mandatory Guidelines.

NRC response: The NRC concurs that partial specimens should not be combined and has revised § 2.4(g)(11) of Appendix A accordingly. That section now requires each licensee to predetermine a quantity of urine that it will require of all people submitting specimens in its testing program. This quantity should take into account all analyses and reanalyses provided for in the licensee's FFD policy. It should provide for at least the 30 milliliters needed for testing at the licensee's HHS-certified laboratory plus an additional amount needed for testing for any drugs in addition to those specified in § 2.1(a) of Appendix A. Licensees that authorize split specimens or conduct onsite testing should also provide for these needs when determining the required quantity.

In cases where an employee produces a specimen of smaller quantity than that predetermined by the licensee, the specimen should be used to the extent possible to meet the testing requirements in the following order of priority: testing at the HHS-certified laboratory, provision for a split specimen if authorized by licensee FFD policy, and on-site screening testing. That is, if the licensee conducts onsite screening testing and, for example, an employee can produce of specimen of only 30 to 35 milliliters, the licensee should not test that specimen on site but instead should send the specimen to its HHS-certified laboratory for testing. In this example, there would be no split specimen for the donor to challenge the results on the primary specimen. With respect to the combining of partial specimens, the NRC now believes that partial specimens should not be combined and no partial specimen should be discarded. Instead, specimens of less than 30 milliliters should be sent along with any subsequent specimen(s) collected during that collection process for testing at the HHS-certified laboratory and each specimen should be analyzed separately. The rule has been changed accordingly.

16. *Comments About Testing for d and l Isomers.*

Several commenters responded to the proposed requirement that specimens that have a positive GC/MS test result for amphetamines must be tested for *d* and *l* isomers. Some commenters supported the new requirement. Because amphetamine positives are so few, these commenters predicted that the additional test would have minimal impact on licensees

and may serve to spare an employee with a false positive from the stigma of questioning. Other commenters disagreed with the proposed new policy. Some of these commenters maintained that some laboratories use a second testing device that can distinguish between a true and a false positive due to legal medications. These commenters argued that additional tests would increase costs and lengthen turn-around time. Another commenter wondered if HHS-certified laboratories could be expected to provide routine quality control and inspection criteria when *d* and *l* isomer testing is performed.

NRC response: After weighing the potential benefits and costs, the NRC has decided to adopt HHS's Technical Advisory of March 11, 1991, and require that specimens having a positive GC/MS test result for amphetamines be tested for the *d* and *l* isomers. This test is essentially another GC/MS confirmation test to determine if legal drugs containing amphetamine compounds caused the positive drug test. In some cases the MRO may be able to look at the concentration levels for amphetamine and methamphetamine obtained during the GC/MS confirmation testing, as well as information provided by the donor, to make the determination. Frequently, however, additional information is required. In these cases, it is currently necessary for the MRO to request the additional GC/MS test for the *d* and *l* isomers. This can be done on a case-specific basis or under a blanket request.

The NRC's adoption of this requirement in effect mandates a blanket request which will expedite the availability of information to the MRO. This, in turn, should permit more timely responses to potential safety problems. Assuming that MROs are currently obtaining information on *d* and *l* isomers from all GC/MS positives for amphetamines, the additional burden on licensees is expected to total only a few tests per year industry wide, a number that will create an insignificant additional cost.

The NRC also notes that information obtained from HHS indicates that the commenter's assertion that some laboratories use a second testing device that can distinguish between a true and false positive due to legal medications is mistaken. The general laboratory practice is to use the EMIT screen, which has some cross-reactivity problems, for the screening test, then rescreen specimens with a positive screening test result with the Abbot TDx, which is more specific for the *d* isomer and has less cross-reactivity. This double screening for amphetamines is followed by GC/MS testing. This process would not eliminate prescribed amphetamines, but would eliminate most cross-reactivity caused by over-the-counter medications.

17. *Comments About Forwarding Split Specimens for Testing.*

Section 2.7(k) of Appendix A formerly required licensees to forward split specimens for testing on the same day that the employee requested that the split specimen be tested. Three commenters recommended this provision be revised because licensees found it difficult to meet this same-day requirement when, for example, the employee's request is received late in the day.

NRC response: The NRC agrees with these commenters and has revised § 2.7(k) accordingly. This section now requires licensees to forward the split specimen to another HHS-certified laboratory for testing as soon as practicable, but in no case more than three weekdays following the day of the employee's request. The Commission has also revised this section to make explicit that split specimens are to be tested only at the request of the employee.

18. *Comments About Extrapolation of Alcohol Testing Results.*

A number of commenters addressed the proposed requirement that alcohol test results between 0.02 and 0.04 percent blood alcohol concentration (BAC) be forwarded to an MRO for back extrapolation to determine whether the employee's blood alcohol concentration was

impermissibly high during a duty period. Most of the commenters opposed the proposal and recommended that it be deleted from the rule. A few commenters supported the proposed extrapolation requirement but requested guidance as to how the procedure should be carried out.

NRC response: The NRC proposed the back extrapolation requirement because it was concerned that some licensees have not taken appropriate action after obtaining alcohol test results just below 0.04 percent BAC after the tested employee has been at work for several hours. These results allow very little doubt that the employee has had an unacceptably high BAC, and has probably been impaired, at some time during the work period. These situations must prompt an investigation as to whether the employee has violated the licensee's FFD policy. Although the NRC continues to consider back extrapolation to be an appropriate technique to deal with such situations, it has determined that it is desirable to set a standard that does not require an MRO's evaluation.

In place of a back extrapolation requirement, the NRC has revised § 26.24(h) to adopt a standard for declaration of a positive test result based on BAC levels above 0.02 percent. This section now requires that findings of BAC levels of 0.03 percent or greater after the worker has been on duty for one hour or 0.02 percent or greater after the worker has been on duty for 2 hours be declared violations of the licensee's FFD policy. This revision eliminates the need for the MRO to perform back extrapolation. Licensees should assure that their employees are aware of this rule change and its implications. Licensees are also reminded that they should continue to make their employees aware of the individual differences in alcohol metabolism, the effects of food on metabolism rates, and other physiological variables that effect blood alcohol content.

19. *Comments About Sanctions for Alcohol Violations.*

Commenters objected to making sanctions for violations of licensee FFD policy associated with alcohol abuse equivalent to those for illegal drugs. Some of these commenters recommended that licensees be allowed to continue to handle FFD policy violations involving the use of alcohol on a case-by-case basis. Other commenters asked what sanctions should be imposed when back calculation for blood alcohol concentration results in a finding of FFD policy violation.

NRC response: The NRC has always intended that licensees have sanctions for alcohol abuse that will adequately deter such abuse. Noting the continued positive alcohol test results, which are direct evidence of impairment, and some licensees' lack of effective sanctions for alcohol abuse, the NRC believes that it must establish minimum sanctions for alcohol abuse. The NRC's review of licensee FFD program performance and the relevant literature confirms that the minimum action needed to deter alcohol abuse is a 14-day removal from duty, referral to the EAP, follow-up testing, and the knowledge that a second confirmed positive test result will lead to denial of unescorted access for a minimum of three years. Based on these considerations, the NRC has revised § 26.27(b) to make the required sanctions for alcohol abuse equivalent to those for confirmed drug violations.

With respect to sanctions based on back calculation of alcohol BAC, the NRC has decided not to require back calculation, as discussed in item 19, above. The same sanctions that apply to any other alcohol-related violation will apply in these cases.

20. *Comments About Sanctions for Other FFD Policy Violations.*

Commenters inquired about what sanctions should be imposed for abuse of over-the-counter drugs and when specimens are found to have low temperature or low specific gravity.

Two commenters asked whether a result of a test at an HHS-certified laboratory's limit of detection (LOD) that is deemed "positive" should result in a sanction. Commenters also requested clarification on what sanctions should apply to FFD program personnel and individuals who are suspended under Part 26. In particular, they requested clarification of the requirements pertaining to employees who are suspended from unescorted access but are still in a work status during their suspension period and remain covered by the FFD program with respect to applicable behavioral observation, chemical testing, and sanctions for violations of FFD policy. Commenters were concerned that the proposed requirement could be construed to mean that a contractor employee, denied access by the licensee but still employed elsewhere by the contractor, would have to remain covered by the licensee's FFD program.

NRC response: The FFD rule does not specify sanctions for abuse of over-the-counter drugs except to require that licensees' FFD policies must include sanctions that effectively deter such abuse. Licensees should rely on MRO judgment regarding the nature and magnitude of such abuse and in determining the appropriate response.

Low specific gravity or low temperature by themselves do not represent policy violations. Additional information, such as the donor's fluid intake and core body temperature, should be obtained. That information, along with the information obtained from specimen validity and LOD testing, must be evaluated by the MRO to determine if there is a violation of the licensee's FFD policy. A specimen of questionable validity that shows evidence of dilution must be tested at the HHS-certified laboratory's LOD as required by § 2.7(e)(4) of Appendix A. If the test indicates the presence of illegal drugs or metabolites, the MRO should determine that the donor used drugs in violation of the licensee's FFD policy, and may determine that the donor attempted to subvert the testing process. The sanctions set forth in § 26.27(b) and (c) apply, depending upon whether subversion was involved. If, however, the LOD testing produces a negative result, the MRO can exercise discretion by determining that it is a true negative or by determining that there is still a question and more information (potentially including an observed recollection) is required.

The NRC believes that any act that would cast doubt on the honesty and integrity of FFD program personnel should result in removal from the FFD program responsibilities listed in § 26.2. The § 26.27(b)(3) requirement that employees who are suspended, but still in a work status during their suspension period, remain covered by the FFD program with respect to applicable behavioral observation, chemical testing, and sanctions for violations of FFD policy has been revised to clarify that only people who are still in the employ of the licensee need be covered.

21. *Comments About Testing for Adulteration and Dilution.*

The NRC received comments on a wide range of specimen validity issues. Commenters provided both positive and negative responses regarding requirements to testing for dilution and adulteration. Several commenters addressed the NRC's request for comments regarding whether tests for masking agents and adulterants should be required, both supporting and opposing responses were received. Two commenters disagreed with the proposal to test suspect specimens at one-half of the cut-off levels specified for each drug instead of at the HHS-certified laboratory's limit of detection, and one commenter recommended that limit of detection testing should be the standard for all testing. Clarification was requested as to the application of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to the use of creatinine, specific gravity, and pH testing to determine specimen validity.

NRC response: The NRC has determined that there are substantial benefits derived from specifying minimum requirements for the determination of specimen validity and has decided to adopt changes made to the HHS Mandatory Guidelines and changes to laboratory procedures directed by HHS under the NLCP. The NRC believes that these changes are needed to reduce potential subversion of the testing process. NLCP Program Document #35 establishes standards for specimen validity testing by the HHS-certified laboratories that includes creatinine, specific gravity, pH, and nitrites. The NRC has decided to require, consistent with specimen validity testing standards established by HHS, the use of tests for creatinine, specific gravity (only when the creatinine concentration is abnormal), pH, and nitrites to determine specimen validity at the HHS-certified laboratories. The NRC will require the use of tests for creatinine, pH, and nitrites for specimens being tested on site; these can be accomplished using currently available HHS/FDA approved non-instrumented testing devices, such as “dip sticks.”

The NRC agrees with commenters that HHS-certified laboratory LOD standards, rather than one-half the cut-off levels specified for each drug, should be used to test specimens of questionable validity. The NRC declines to require that all specimens be tested at LOD, because that would require GC/MS testing (a costly process) of all specimens. Screening tests (a less expensive process), which are intended to eliminate specimens that are clearly negative from further testing, will continue to be used. However, specimens of questionable validity, such as those with low creatinine and specific gravity, need special processing, which may include LOD testing. Currently, CLIA is not applicable to the use of creatinine, specific gravity, pH, and nitrite testing to determine specimen validity in workplace drug testing.

22. *Comments About Chemical Testing at HHS-Certified Laboratories' Limits of Detection.*

Several commenters responded to the NRC's proposal to require licensees to test specimens found to be of questionable validity at their HHS-certified laboratory's limit of detection. Several commenters opposed this requirement citing increased costs, problems with the technical defensibility of the procedure, problems of cross-contamination during testing and differences in LOD standards among laboratories that may cause inconsistent test results, and contended that HHS does not sanction the procedure. One commenter supported the proposed requirement, stating that it is an effective and technically defensible procedure. Others supported it only for follow-up tests and appeals. Other commenters requested additional guidance regarding procedures and protocol for LOD testing.

NRC response: After reviewing information pertaining to the concerns raised by commenters, the NRC continues to believe that LOD testing of questionable specimens is a cost-effective and technically defensible means of reducing the incidence of successful subversion of the testing process. LOD testing of the expected small number of questionable specimens (those not clearly valid or invalid) will provide a cost-effective means of protecting those being tested from incorrect conclusions about the validity of their specimens while providing an effective deterrent from attempts to subvert the testing process by specimen dilution. The NRC also believes that HHS-certified laboratories are quite capable of preventing cross-contamination of specimens when conducting LOD testing. Furthermore, the NRC believes that differences in LOD capabilities across HHS-certified laboratories should not affect the defensibility of LOD testing results. The NRC, however, expects that licensees will consider HHS-certified laboratories' LOD capabilities when selecting their testing laboratories.

Each HHS-certified laboratory has a limit of detection for GC/MS testing that is the lowest concentration of an analyte that the laboratory can reliably detect and accurately quantify; the LOD for each drug will vary from lab to lab and may vary over time. This variance

is due to several factors, such as the method chosen to extract the drug(s) from the urine and the method chosen to ionize drug molecules. HHS-certified laboratories are able, through the use of LOD levels, to reliably identify in a forensically valid manner drug metabolites at the low concentration levels found in dilute specimens. It should also be noted that the HHS Mandatory Guidelines currently permit testing to determine specimen validity (see section 2.1(c) of the HHS Mandatory Guidelines) and also permit LOD testing to confirm the presence of the drug or drug metabolite during retesting (see section 2.4(l) of the HHS Mandatory Guidelines).

In recognition that LOD testing applies only to GC/MS testing, the NRC has modified the proposed new § 2.7(e) of Appendix A to require licensees to subject specimens that are determined to be of questionable validity that show evidence of dilution to screening testing using FDA-approved analytical kits having the lowest concentration levels marketed for the screening technology being used. The responses of the questionable donor specimens must be compared to the acceptable range of negative screening control responses and those that respond greater than the negative control response (e.g., indicating the presence of drugs) must be subject to LOD confirmation testing. The important point is that specimens that are determined to be of questionable validity should not be tested at the normal cut-off levels. Also, specimens that are found to be out of specification may be GC/MS tested at LOD regardless of the screening test result if the MRO continues to question the reason for the specimen dilution.

23. *Comments About Temperature.*

Commenters both supported and opposed the proposed narrower temperature range of 94°F-100°F for acceptable specimens. Some commenters noted that specimen temperature may be reduced to below the acceptable range by several factors unrelated to subversion such as room temperature, specimen container temperature, time from urination to temperature measurement, and accuracy of the thermometer. They also noted that the proposed temperature range would make subversion more difficult. Other commenters maintained that a narrower temperature range would burden the licensees with an increased number of recollections under observation, and also noted that the narrower temperature range is not consistent with HHS or DOT guidelines. One commenter noted that the rule does not address cases in which the specimen donor's oral temperature is normal (37°C/98.6°F), but the specimen's temperature is less than the acceptable lower limit of 34°C/94°F.

NRC response: Upon reconsideration, the Commission has decided not to adopt a narrower temperature range. Insufficient data exists showing whether there would be a significant number of true positives identified using the more restricted temperature range that are currently classified as negatives. Thus, it is unclear whether the benefits of identifying these true positives outweighs the cost of additional confirmatory testing for eliminating false positives. The existing temperature range requirement, which is consistent with the HHS Guidelines, is therefore retained in the final FFD rule.

The NRC recognizes that several factors, including ambient temperature and sample size, affect the temperature of a specimen. Licensees are expected to take precautions to reduce the potential effects of these factors, such as providing a reasonable ambient temperature, measuring the temperature as soon as possible after collection, and using accurate temperature measuring devices. If the licensee uses a traditional temperature measurement device, then the two most critical factors are time and ambient temperature. If licensees can measure the temperature within two minutes, they should maintain the ambient temperature at not less than 65°F. If licensees need three minutes to measure the temperature, they should maintain the ambient temperature at not less than 70°F. The use of a peak temperature measuring device which records the specimen's highest temperature in the

specimen collection cup during urination would eliminate the time and ambient temperatures as critical factors. Licensees should use specimen collection cups (considering size, shape, material, and temperature) that do not contribute to the decline of specimen temperature. In addition, specimens smaller than 30 cc require the collection of additional specimens, and each specimen should have its temperature measured and recorded with the understanding that smaller specimens may be cooler. The NRC continues to believe that measuring specimen temperature is an inexpensive and effective way to reduce the possibility of subversion. The current range of 90°F to 100°F used by HHS and DOT responds to the broad range of programs and circumstances under which collections occur in the industries served by these agencies. The nuclear industry experience has some examples to show that the original standard has not achieved its intended purpose. Therefore, the NRC staff will continue to monitor the nuclear industry's experience in this area to determine if this change should be reconsidered in the future.

24. *Other Subversion Issues.*

The NRC received several comments regarding the proposed shorter time limit on the interval between employee notification and specimen collection. Three comments supported the shorter interval, citing as evidence the experience of several plants where there was a significantly lower number of specimens containing drugs below the cutoff levels when a limited time period was enforced than when an unlimited time period was allowed. However, another commenter cited evidence that it is still possible for dilution to occur with a 15-minute notification time. Two commenters noted that it is difficult to assess whether a dilute specimen is the result of an intentional effort aimed at subverting the testing process. One of these commenters noted that there is no way of proving an intentional dilution and that efforts to overcome a "shy bladder" are likely to result in a dilute specimen.

NRC response: The NRC believes that a shorter interval of time between notification and testing provides less opportunity for subversion attempts and expects that licensees will use the flexibility provided in the rule to develop approaches that will limit opportunities to subvert the testing process. The NRC agrees that it is not possible to determine the basis for a dilute specimen (unless the specimen is outside the range possible for any urine specimen). For this reason the NRC is requiring that such specimens be tested under the process described in § 2.7(e) of Appendix A. When the validity of the specimen cannot be determined, another specimen is to be collected as soon as possible. In addition, if after reviewing the results of the processing described in § 2.7(e) the MRO determines that there is no reason to believe there was an attempt to subvert the testing process, an observed collection is not required at subsequent testing occasions.

The NRC desires to provide guidance concerning a potential subversion technique that has become an issue for several licensees - claims of ingestion of hemp food products as the basis for a positive marijuana test. Food products containing hemp seeds or extracts have produced marijuana positive test results, even though the seeds were supposed to have been sterilized to remove the THC metabolite. The NRC endorses the Federal policy in this matter that was published by the Department of Transportation, with the concurrence of the Departments of Justice and Health and Human Services and the Office of National Drug Control Policy. MROs must never accept an assertion of consumption of a hemp food product as a basis for verifying a marijuana test negative. Consuming a hemp food product is not a legitimate medical explanation for a prohibited substance or metabolite in an individual's specimen. When a specimen is positive for THC, the only legitimate medical explanation for its

presence is a prescription for marinol. As required by § 26.21, licensees must ensure that persons covered by their FFD program understand the policy and that they are responsible for what they ingest, even if it is marketed as a legitimate product.

25. *Comments About Violation Determination/Reinstatement.*

Commenters recommended that employees with laboratory confirmed positive test results should be removed from duty until they are interviewed by the MRO. This would prevent them from being in the protected area until a determination is made by the MRO and could be an important safety measure because MROs often have difficulties in contacting individuals to arrange for consultation. Other commenters noted problems in making a final determination when the donor of a laboratory confirmed positive test result cannot be contacted by the MRO for an extended period.

NRC response: The NRC believes that permitting automatic suspension of access based solely on a laboratory confirmed positive test would be an unnecessary abridgement of individual rights, and would achieve little enhancement of safety. The NRC also believes that the MRO and the licensee have sufficient flexibility under the original rule to address safety concerns in situations in which people who have laboratory confirmed positive test results have failed to contact the MRO after being requested to do so. In response to commenters' concern about situations in which the MRO cannot interview individuals who have had laboratory confirmed positive test results, the NRC has revised § 2.9(c) of Appendix A. These revisions provide guidance regarding the disposition and reporting of results when a worker leaves the employ of the licensee or for other reasons cannot be interviewed by the MRO after a laboratory confirmed positive test result. Provisions are also included for subsequently correcting the employment records when appropriate.

26. *Comments About Spousal Use of Prescription Drugs.*

Commenters agreed with the NRC's policy of permitting the MRO to use prudent judgment in dealing with sensitive issues such as spousal use of prescription drugs. One commenter strongly supported the NRC's formal statement of its approach to spousal use of prescription drugs, noting that MRO judgment should be relied upon in these cases.

NRC response: The NRC concurs that it is prudent to rely on MRO judgment in these cases and notes that prudent actions should in all cases be taken to assure that there is no substance abuse or fitness problem that may jeopardize public health and safety.

27. *Comments About Psychological Impairment.*

One commenter requested that the NRC provide specific guidance on when licensees should deny unescorted access in cases where workers appear not to be fit for duty for psychological as opposed to substance abuse reasons.

NRC response: The rule's general performance objectives in § 26.10(a) and (b) provide general guidance regarding how FFD programs should handle workers who appear unfit for duty for any reason. In addition, § 26.27(b)(1) requires that personnel whose fitness may be questionable be removed until determined to be fit. That may be the result of any condition noted in §§ 26.20(a) and 26.24(a)(3), or displays of aberrant behavior, violence, etc. that would cause doubt as to whether the worker's responsibilities would be met safely and competently. Licensee FFD programs should be designed to address all situations that may cause workers to be unfit for duty. Regardless of the cause of the fitness problem, appropriate action should be taken to assure that an individual does not work with any condition that would jeopardize the health or safety of him or herself, other plant personnel, or the general public.

28. *Comments About Fatigue or Other Impairment.*

One commenter requested guidance with regard to allowing employees on site with escorted access when they are not fit for duty either because of fatigue, alcohol, or for other reasons.

NRC response: The rule permits escorted access when a person is not fit. This provision is primarily intended to prevent a licensee from being automatically in violation if it determines that the person is unfit while at work. It also permits a licensee to use a person who may otherwise be unfit. This means that the licensee is aware of the worker's condition and has determined that its needs must be met by using this person. It also means that the licensee can accommodate the situation to ensure there is no safety hazard to the worker, other workers, and the public. Licensees are expected to use prudent judgment in allowing employees with a condition that makes their fitness for duty questionable to perform work under escort. The NRC recognizes that an employee's specific skills and/or expertise may make such an accommodation desirable in exceptional cases.

29. *Comments About Protecting Workers Rights.*

Some commenters made recommendations that information available to an employee pertaining to his or her FFD policy violation should be limited to test results and summary data on the violation determination and that information on an employee's self-referral to an EAP should not be made available to the employer. Other commenters expressed concerns that frequently there are legitimate causes for dilute specimens and, hence, that subsequent collections of specimens under direct observation may be inappropriate in these cases.

Commenters also had specific inquiries regarding workers' rights: 1) Can an MRO order a split specimen to be tested? 2) Does the NRC expect licensees to remove employees from unescorted access pending for-cause test results? 3) How should licensees handle worker confidentiality and privacy issues when establishing a prior history of substance abuse and does prior history of abuse include self-referral to an EAP for substance abuse? 4) Is a prior positive drug test in a DOT-mandated substance abuse program included in a history of substance abuse? 5) What records can be retained and used for current decisions?

NRC response: The NRC believes that an employer should provide to an employee copies of all relevant records related to the determination of the employee's FFD policy violation upon that employee's request. Self-referrals should result in a notification of the employer, as required by § 26.25, only if the EAP counselor determines, based on information obtained from the self-referral, that the individual constitutes a threat to the health and safety of himself or herself or to others.

The NRC agrees that it is difficult to determine the basis for a dilute specimen (unless the specimen is outside the range possible for any urine specimen) and that there are legitimate reasons for most dilute specimens. The NRC is requiring that dilute specimens be tested under the special processing described in § 2.7(e) of Appendix A, unless the specimen's specific gravity is less than 1.001 where deliberate dilution is established by policy. If this special processing detects no evidence of drugs or drug metabolites and the MRO has no reason to believe that the dilution may have been an attempt at subversion, the MRO can determine that there is no violation of the licensee's FFD policy and declare a negative test result. When the validity of a specimen cannot be determined, another specimen must be collected as soon as possible under direct observation.

To answer the commenters' specific questions: (1) An MRO can order a split specimen to be tested only if requested to do so by the specimen donor. (2) If there is any reason to question an individual's fitness, he or she should be removed and not permitted to return to

unescorted access status until the fitness-for-duty issue is satisfactorily resolved and the individual is determined to be fit. Where access is pending a determination of fitness, the licensee should be discreet about the reasons for the individual's absence from work. (3) Files on testing of workers and responses to suitable inquiries must be maintained by and divulged to only those persons having a legitimate need to know, as described in § 26.29. In self-referral cases, the information provided by the individual would be regarded as medical treatment information and not disclosed under suitable inquiries (see NUREG-1354). Unless the person is a threat to himself, herself, or others (including threats to public health and safety resulting from his or her work at a nuclear power plant) the information should be kept confidential and need not be included in the individual's history of substance abuse. 4) A positive test result under a DOT program, or any employer program, would constitute a history of substance abuse. See the definition of history of substance abuse for other matters that constitute such history. 5) A decision by an MRO must be based on all relevant information the MRO obtains with respect to the test results being reviewed. That is, a previous positive test result (or policy violation) must not influence an MRO's current decision as to whether a current specimen is positive or there is some other FFD policy violation, such as attempted subversion. However, the history of substance abuse, without regard to the interval between violations, must be included in the imposition of the current sanctions, as required by §26.27. Revisions to §26.71 have been made to make it clear that records pertaining to a determination of a violation of FFD policy must be retained at least 5 years, whereas records pertaining to revocation of authorization to perform activities within the scope of Part 26 must be retained for the duration of the license. With regard to relevant information, unusual situations, such as described under "Comments About MRO Issues" (No. 32, below), may include screening test results. Also, licensees are reminded that all records of temporary removals or suspensions taken under the provisions of 10 CFR 26.24(d)(2) must not be retained if the HHS-certified laboratory fails to confirm an onsite presumptive positive screening test and reports the test results as negative. Furthermore, any personal recollections of such temporary removals must not be considered.

A revision to § 26.29 has been made to assure that personal FFD information is protected. The revision requires that the subject individual's representative be designated in writing for specified FFD matters. The designation should be limited in duration, purpose, and scope and must not be a general "release" that would, for example, permit a union official to automatically represent a member/subject individual.

30. *Comments About Appeals and the Testing of Split Specimens During Appeals.*

Commenters recommended changes to or the deletion of proposed rule revisions that would clarify that applicants for unescorted access must have the right to appeal FFD policy violations. They also asked whether the rule requires that an appeal must be conducted by more than one person and whether the difficulty to clearly determine whether a person has deliberately hydrated him or herself could adversely affect the appeals process.

Commenters also raised a number of issues regarding the testing of specimens for appeals. Because the splitting of specimens is done at the option of licensees, one commenter recommended that the rule indicate that the lack of a split specimen should not affect the outcome of appeals when retest of primary specimens are positive. Commenters had opposing opinions regarding payment for the reanalysis of primary specimens and the analysis of split specimens when employees pursue appeals. Commenters also asked if using a second laboratory to test split specimens would require an audit of that laboratory, if a licensee could direct the worker requesting a specimen reanalysis to use the licensee's back-up lab, and whether licensees would be required to inform workers whose test results were confirmed

positive that they can choose to have the original aliquot reanalyzed as well as have the split specimen analyzed at a second testing laboratory.

NRC response: The NRC believes that the potential consequences of a determination that a licensee's FFD policy was violated by an applicant for unescorted access, which could include long-term exclusion from the nuclear industry, are sufficiently severe that full appeal rights for applicants are warranted. Section 26.28 has been revised accordingly. In response to the comment regarding whether an appeal can be conducted by one person, the use of the word "persons" in § 26.28 is intended to indicate that appeals must be conducted by more than one person. In the NRC's view, allowing appeals to be conducted by one person would tend to compromise an employee's right to independent and impartial appeals of FFD policy violations.

The fact that it is difficult to clearly determine whether a person has deliberately hydrated himself or herself should not adversely affect the appeals process. When there is an indication of possible hydration, the evidence of such hydration, to the extent it exists, must be weighed and considered along with all other information that led to the original determination of a FFD policy violation.

The NRC declines to revise the rule to indicate that the lack of a split specimen should not affect the outcome of an appeal. Whether or how the lack of a split specimen should be considered in employment actions should be left up to the adjudicators of those actions.

In the case of split specimens, the employee essentially "owns" the specimen. Section 2.7(k) of Appendix A gives the employee the right to have the split specimen analyzed at a laboratory of the employee's choice in cases where his or her primary specimen has produced a confirmed positive test result or the primary specimen has been determined to have been subject to adulteration, dilution, or other means of testing subversion. Split specimens can be tested only at the tested individual's request; the MRO does not have the discretion to order the testing of the split specimen unless the employee requests it. The NRC understands that laboratories are reluctant to test individual specimens and desire some sort of contractual agreement which, in effect, would limit the worker's choice of a laboratory for analyzing the split specimen. While the licensee is free from responsibility of auditing the HHS-certified laboratory chosen by the worker, the licensee may have some concerns that the laboratory does not have equivalent technical capabilities to those of the laboratory with which the licensee has a contract (e.g., it may have a higher LOD). Licensees could assure the use of a laboratory with equivalent technical capabilities by paying for the analysis of the split sample.

Licensees should fully inform their employees of their rights to appeal FFD policy violation determinations. Licensee awareness training programs should comprehensively describe these rights and the licensee's appeals process; furthermore, workers who have been cited for a FFD policy violation should also be made aware of these rights. These rights include the elements of appeals specified in § 26.28, the right to have the original specimen reanalyzed, as granted by § 2.9(e) of Appendix A, and the right to have a split specimen tested if the licensee has provided for the collection of split specimens, as permitted by § 2.7(k) of Appendix A.

31. *Comments About Awareness and Supervisory Training.*

Commenters noted that some licensees have chosen to consolidate their awareness and supervisor/escort training programs so that everyone with unescorted access is trained to the highest level of knowledge and can act as an escort. Commenters also requested that the NRC consider adopting the same cycles for awareness and supervisor training so that the implementation and tracking of a combined training program would be simplified for those licensees who choose to consolidate the two programs. It was specifically recommended that

the 24-month frequency for awareness training outlined in § 26.21 be extended to the training of supervisors and escorts.

Several commenters objected to or requested clarification of specific differences, such as completion periods, in training requirements between licensee and contractor supervisors, and new and transferred supervisors. There were also several comments regarding the need for annual supervisory refresher training or testing and alternative methods of training or testing.

NRC response: The rule revisions regarding awareness and supervisor training reflect what the NRC considers to be the appropriate schedule and level of training for workers in the general plant population and for supervisors and escorts. Licensees have the flexibility to create one training cycle by training all personnel at the highest level of frequency. The importance of supervisors and escorts in assuring the effectiveness of the FFD program requires that they have a yearly refresher requirement.

As permitted in the original rule, supervisors employed by licensees who are granted an initial supervisory assignment will continue to be allowed to complete the initial training within a period of 3 months to prevent the possibility that promotions to supervisor within the licensee's workforce might be impeded due to rigid training requirements. The shorter 10-day time limit for supervisors employed by contractors to be trained following their initial supervisory assignments is justified because of the higher rate of positive tests among contractor personnel since the rule has been in effect and also because of the temporary nature of the appointment to supervision in many contractor organizations. Temporary appointments have in some instances resulted in supervisors employed by contractors never being trained in their supervisory responsibilities. The NRC also believes that training in the subject areas specified in § 26.22, especially in behavioral observation and initiating corrective actions, could better detect the substance abuse problems with the contract workforce. (The NRC has previously recognized some of the difficulties of training contract supervisors; see item 11.3.4 of NUREG-1354, which addresses rotation of supervisory responsibilities, and item 3.3 of NUREG-1385, which recommends acceptance of prior training.) The NRC believes that the change will help prevent situations in which contract supervisors are not trained in their supervisory responsibilities, and notes that lack of this training may have contributed to the historically much higher rate of positive tests among contract personnel.

The NRC realizes that refresher training may include other types of training methods in addition to classroom training. These may include reading materials and computer based training, for example. The NRC declines, however, to specify the method of training. In the revised § 26.22(c), the NRC is allowing a written examination that demonstrates an adequate knowledge of pertinent FFD material and issues to be used in lieu of refresher training for supervisors in two out of every 3 years. This revision should provide licensees with flexibility and reduce the burden that an annual classroom refresher course might impose. The NRC will not be developing a standard annual written refresher training exam. It would be inappropriate for the Commission to do so because this type of exam would have to include site-specific matters such as the roles and responsibilities of specific licensee personnel, procedures for initiating corrective actions, and procedures for making referrals to the EAP, all of which differ among licensees.

32. *Comments About MRO Issues.*

Several commenters addressed the issues of independence of MROs from the HHS-certified laboratories, onsite testing services, and blind performance testing specimen providers. Some commenters supported the proposed revisions to the rule which require this

independence. Others requested clarification that further defines the limits of the relationship between MROs, including contracted MROs, and the laboratories and onsite testing services.

Some commenters suggested that the MRO review only positive results, rather than both positive and negative results, and that FFD program staff be allowed to conduct the accounting for completed tests. Other commenters asked if telephone interviews are appropriate in determining positive test results in cases other than opiates and noted the increasing importance of training and certification of MROs due to the evolution of drug testing and the increased responsibilities of MROs. Some commenters objected to the proposed rule change that would require MROs to provide written notification of positive test results to licensee management in writing. They argued that having to provide notification in writing may delay action against a violator or adversely affect test result confidentiality.

Commenters also made recommendations concerning what should constitute "clinical signs" and "clinical evidence" of opiate abuse that § 2.9(d) directs MROs to examine when verifying laboratory confirmed positives for opiates. One commenter suggested that clinical signs of opiate abuse be limited to needle tracks and admission of use. Another recommended that, if "substantial evidence of a significant lack of reliability or trustworthiness" were to remain as one type of clinical evidence of opiate abuse as the Commission proposed, then that concept should be more clearly defined.

NRC response: The revisions to the rule regarding MRO independence are adaptations of changes HHS made to its Mandatory Guidelines and are intended to assure that there is no conflict of interest between the MRO, onsite testing and blind performance testing features of licensee programs, and the HHS-certified laboratories. The NRC believes the rule to be sufficiently clear on the requirements regarding conflict of interest and that no further clarifications are needed. The requirements apply to any MRO reviewing any test results of specimens collected under Part 26 regardless of whether the MRO is an employee of the licensee, an "independent" contractor, or an employee or partner in an MRO service. This also applies to any FFD program reviewed and accepted by a licensee under the provisions of § 26.23.

The NRC agrees that the "accounting" function to assure that all specimens collected are tested may be performed by the MRO's staff, as permitted by § 2.7(h)(2). The NRC believes, however, that extending this function to the FFD program staff would be inappropriate because test results are required to be sent to the MRO only, and involving FFD program staff in this function could create the potential for conflicts of interest.

Contrary to some commenters' recommendations, the NRC believes that both negative and positive results must be reviewed. The MRO has always had access to all testing results. The HHS Mandatory Guidelines specify that all results reported by the laboratory must be reviewed at a general level by the MRO. Before sending test results to licensee management, the MRO, or technically qualified staff under the MRO's supervision, is expected to review the negative results for any anomalies, false negatives, or low specific gravity or creatinine results that indicate a need for reanalysis, etc; documentation of negative results may be signed or rubber stamped by the MRO or a technically qualified person. The MRO is responsible for the proper review of negative test results. Positive test results, in contrast, require a careful in-depth and individual review; positive results must be signed by the MRO. A legible photocopy of Copy 4 of the OMB-approved Custody and Control form (or a look-alike form) may be used in lieu of producing a new record provided the verified substances or evidence of subversion are clearly indicated. (This modifies the NRC's previous position on the need for review of negative results as set forth in item 5.8 of NUREG-1385, which incorrectly indicated that the MRO need

not review negative test results and indicated that review of negative results to determine if there was a problem was discretionary.)

With respect to telephone interviews, NUREG-1385 explains that in some cases not involving opiate abuse, the MRO could discuss the test results with the individual by telephone, provided suitable precautions are taken to confirm identity and protect the information as required by § 26.29(a) and (b). With respect to the requirement that MROs provide a written record of positive test results to licensee management, this requirement is an adoption of the HHS Mandatory Guidelines and does not preclude initial notification by telephone or other means.

The NRC agrees that the MRO plays a vital part in assuring an effective program and recognizes that there are currently existing certification programs intended to assure a desired level of MRO competency. While the NRC also recognizes that this may be an area requiring regulatory action in the future, the NRC and HHS are not considering developing requirements regarding MRO certification at this time.

The NRC agrees that designating "substantial evidence of a significant lack of reliability or trustworthiness" as a type of clinical evidence of opiate abuse in § 2.9(d) would have created difficulties and has withdrawn this proposed wording. The NRC believes that behavioral and psychological signs of acute opiate intoxication or withdrawal should be part of clinical evidence. Also, admission of non-prescribed opiate use has been added to this section as another example of clinical signs of abuse that MROs can consider when verifying confirmed positive test results for opiates.

The Commission desires to comment on the MRO's responsibilities in regard to unusual cases. Although the FFD rule is quite prescriptive, it does provide flexibility to deal with unusual cases where a "business as usual" process will not work. In many of the unusual cases which are known to the NRC, MROs have had to take more active roles in the testing process by trying to determine what information is needed and how it should be evaluated. Abuse of over-the-counter (OTC) medications presents unusual problems that have been mishandled by MROs and licensees. For example, OTC medications used to treat symptoms of colds and allergies frequently contain synthetic methamphetamine, which can cause anxiety, nervousness, and loss of sleep. The synthetic methamphetamine may be abused as a substitute for methamphetamine, a highly addictive stimulant that can cause paranoid and violent behavior and which is replacing cocaine as a drug of choice by many substance abusers. The use of pseudoephedrine tablets for reduction to a concentrated methamphetamine is growing in popularity and frequency. Large concentrations of this OTC medication in urine can result in a presumptive positive screening test for amphetamines that will fail to confirm with GC/MS. Rather than declaring the results negative, the MRO needs to obtain more information and determine if there is a fitness issue that could jeopardize safety. Adding benzodiazapines and barbiturates to the testing panel, while commendable, will not detect the synthetic methamphetamine compound. The MRO should request GC/MS tests for the specific compound of interest; in the example these are usually pseudoephedrine, phsylosphine, or phesyloproproramine. The MRO can then evaluate the observed behavior, the presumptive positive screening test results, the special GC/MS testing, and any information provided by the worker.

The Commission also desires to emphasize that it is the MRO who is responsible for reviewing the information and determining whether a violation of the licensee's FFD policy has occurred. Although the MRO can consult with other MROs and toxicologists, which is advisable in many unusual situations, the evaluation and determination responsibility cannot be passed to others or to a "committee" as has happened. Once the MRO has determined that a violation of

policy has occurred and the screening test results are relevant to that determination, the restrictions of § 26.24(d)(1) concerning access to these test results no longer apply.

33. *Comments About Employee Assistance Program Issues.*

There were a few comments regarding employee assistance program requirements. There were concerns that the proposed requirement to test EAP personnel and the information collection requirements, such as recording the number of referrals to the EAP, would affect the confidentiality of EAP referrals or deter EAP referrals. Some commenters were also concerned that control of EAP personnel and the understanding of industry specific needs may be lost by outsourcing EAP services. There was also a request to clarify the meaning of “early” intervention in § 26.25 regarding the design of employee assistance programs.

NRC response: The NRC does not see any reason why the testing of EAP personnel performing activities covered under § 26.2 should in any way jeopardize the confidentiality of EAP referral. However, the proposed rule change has been revised to eliminate the need to include offsite EAP personnel in the scope of the rule. The NRC understands that EAP performance data are currently collected and monthly reports provided to management by most licensees. The NRC is not aware of any instance where the collection of this type of information has had a negative effect on employees’ use of EAPs. Furthermore, information regarding the number of workers seen and types of problems identified is usually required for billing and insurance purposes and, therefore, is already being collected and reported. The NRC expects licensees to recognize potential problems due to changes in health delivery and insurance that may have negative impacts on FFD program effectiveness and to act to prevent them from creating situations that may threaten public health and safety.

The intent of the requirement for EAP programs to be designed to achieve early intervention is to assure that employees are encouraged to self-refer. The NRC recognizes that early intervention will not be achieved in all cases, but desires to assure that licensees have this as their goal. For example, a policy that equates self-referral to a positive drug test is viewed as discouraging to self-referral. Aspects of the program, such as dependable confidentiality of self-referrals and accessibility are expected to encourage early self-referral. A proven track record and support from successfully treated employees who willingly share their experiences with the workforce have also encouraged self-referrals.

34. *Comments About Oversight Issues.*

The wording in the proposed rule revisions to § 2.4(j) of Appendix A specified that an employee's failure to cooperate with the urine collection or breath analysis process would have to be reported “immediately to the MRO, the FFD Program manager, or to other management having a need to know, as appropriate, for further action.” A commenter asked whether this person would be the employee’s manager. It was also noted that the rule revisions seemed to make the assumption that the FFD program manager has oversight of the MRO and EAP personnel.

NRC response: Reporting a failure to cooperate to the employee’s manager would, in most cases, be a violation of § 2.3(a) of Appendix A.

One of the fundamental aspects of the NRC's regulatory philosophy is that the licensees have the responsibility for operating their facilities, which includes determining which aspects such as MRO and EAP services will be performed by contractors or in-house. Licensees are responsible for managing their FFD programs, and this includes ensuring proper performance by MROs and EAP services regardless of their contractual status. The NRC refers to the person with overall program responsibility as the FFD program manager. If FFD program

responsibilities are dispersed in several organizational elements, then the manager to whom all those elements report would be the FFD program manager.

35. *Comments About Other Management Responsibilities.*

There was a request for clarification regarding how licensees are to satisfy the requirement of making a policy statement addressing FFD policies “readily available to all persons subject to the policy.”

NRC response: Because of legal considerations, it is important that all people covered by licensees’ FFD policies clearly understand and have prior notice of what is expected of them and that they be made fully aware of the consequences of lack of adherence to that policy. One way to ensure that licensees’ policy statements are readily available to all affected personnel is to distribute them during awareness training. Conversely, policies that appear only in FFD procedure manuals but are not provided in a summarized format would not be readily available to employees.

The Commission wishes to emphasize that § 26.20 sets forth minimum requirements for written policies and procedures. Legal challenges against these policies have been successful and very costly to licensees because the policies failed to adequately address the situations that were encountered and the sanctions that were imposed.

36. *Comments About Recordkeeping Requirements.*

Commenters were concerned with the potential need to collect additional FFD program information. They believed that the type of information being considered would provide no additional public health and safety protection or program value. They also thought new information collection requirements would create additional administrative and financial burden on licensees, violate EAP confidentiality and licensee and employee privacy, and contradict the Paperwork Reduction Act.

One commenter noted what appeared to be a discrepancy between the existing record retention requirements of § 26.71(b) that allow records pertinent to findings of FFD policy violations to be disposed of after 5 years and the § 26.27(b)(3) requirement that “any subsequent” FFD policy violation result in removal from Part 26 duties for a minimum of 3 years. The commenter was concerned that, if the record of a first FFD policy is disposed of 5 years after the violation, there would be no record of that violation, and consequently no basis for a three-year removal from Part 26 activities, if the employee had a second violation more than 5 years after the first one. There was also a request for clarification as to when records such as negative test results, quality control records, and instrument maintenance records can be destroyed.

NRC response: The NRC believes that additional data collection may be desirable in the future for regulatory purposes. At this time, however, only the minor additional information collection requirements listed in the proposed rule have been added to the final rule.

The NRC does not agree that there has been a discrepancy between the § 26.71(b) record retention requirements and the § 26.27(b)(3) requirements pertaining to subsequent FFD policy violations. Section 26.71(b) has always allowed licensees to discard after 5 years the supporting documentation that they collect during their determinations of confirmed positive test results and the related personnel actions. Section 26.71(c) has always required licensees to retain for the duration of the license records of persons made ineligible to have unescorted access because of a positive test result. Section 26.27(b)(3) has always required licensees to remove an employee from Part 26 activities for a minimum of 3 years if the employee has a second confirmed positive test result, even though that second violation may have occurred

more than 5 years after the first violation. While licensees may discard the supporting documentation pertaining to most violations after 5 years, they have always had to maintain some kind of permanent record of these violations to be able to comply with § 26.27(b)(3). To ensure a clear understanding of the requirements, these sections have been revised. Section 26.27(c) has been clarified to ensure that information on all FFD policy violations is retained consistent with the § 26.71(b) record retention requirements. Section 26.71(b) has been revised to require a 5-year retention period for records of all FFD policy violations, not just those associated with positive test results. Section 26.71(c) has been revised to require that records pertaining to revocation of unescorted access be retained until the license is terminated.

With respect to records destruction, the NRC does not require that records of negative test results be retained but recommends that appropriate summary information be retained for program administration purposes. Section 2.7(a) of Appendix A requires records of quality control and instrument maintenance to be maintained for at least 2 years. Adequate records of program integrity should be retained to support the validity of positive test results.

37. *Comments About Reporting Requirements.*

Commenters recommended changes to the current reporting requirements including modifying the standard reporting form and allowing alternative methods of reporting. Some commenters thought the proposed changes to § 26.73 that would clarify the requirements for reporting of significant FFD events to be unnecessary. Some commenters also requested clarification on who should report certain significant events and when and how certain significant events should be reported. Other related comments and the NRC's responses are discussed in section 1 above.

NRC response: The NRC will be discussing the standard program performance reporting form with NEI (the developer of the form) to address changes to the form required by the revisions to the rule. These discussions will consider the comments concerning modifications of the form and alternative reporting methods.

The NRC has added wording in § 26.73(a) to provide further guidance as to the types of significant FFD events that should be reported. This revision is necessary because some licensees have in the past reported only those events that were provided as examples in § 26.73(a) and ignored the requirement to report other significant FFD events (see item 10.1 of NUREG-1385). Some of these changes have been added to emphasize the Commission's intent that any act by a FFD program staff member that creates a potential threat to the integrity of a licensee's FFD program must be reported to the Commission. In making this revision, the Commission does not intend to indicate that FFD program personnel bear more attention than other people covered by the rule.

Regarding specific requests for clarification of reporting requirements, there are certain significant events, such as those involving refusal to provide a specimen, subversion, and resignation before removal for program violation that are included in the annual reports submitted under § 26.71(d), and if the event involves a licensed operator, supervisor, or FFD program personnel, the event is also reported under § 26.73(a). The NRC holds each licensee responsible for its FFD program and any program it has reviewed and accepted under § 26.23. For example, if a state employee refuses to provide a specimen being collected by the state, the NRC expects that the state will no longer send that person to the site and will inform the licensee, who in turn will inform the NRC. The NRC declines to be more specific about reporting requirements because there are a considerable number and variety of significant FFD events that could be listed. Unfortunately, many licensees have construed the examples in § 26.73(a) to be all inclusive and have not reported events of the types now specified. The NRC

expects that licensees will respond to the performance expectations of the regulations rather than focusing on minimum compliance. The NRC will not specify who in the licensee's organization must report significant FFD events. The requirement to notify the NRC Operations Center by telephone within 24 hours of discovery remains.

38. *Comments About Auditing of HHS-certified Laboratories.*

Several commenters objected to the proposed new wording that would clarify that licensees must continue to audit nominally every 12 months "testing performed at HHS-certified laboratories." SAMSHA's auditing of the laboratories was the reason most often cited for this objection. It was also pointed out, however, that some testing permitted by the NRC deviates from testing required by the HHS Mandatory Guidelines and, therefore, is not covered by the Substance Abuse and Mental Health Services Administration (SAMHSA) National Laboratory Certification inspection and proficiency programs.

One commenter recommended that existing wording in Appendix B to 10 CFR Part 50 be added to § 26.80 to emphasize that licensee audit reports must not only identify conditions adverse to proper FFD program performance but also recommend corrective action. It was also requested that the NRC relax the requirement that licensees audit program elements affected by changes in procedures or personnel on the grounds that licensees' quality assurance/quality control procedures eliminate the need for such auditing.

NRC response: Part 26 provides licensees flexibility to establish lower cut-off levels than those specified by HHS and to test for additional drugs. These deviations from the HHS Mandatory Guidelines are not covered by the National Laboratory Certification inspection and proficiency programs. The NRC is aware of numerous examples of significant deviations and deficiencies discovered by licensees in testing outside the HHS program. Licensee audits have also discovered problems in areas subject to HHS inspections such as cut-off levels, confirmation testing, and sample handling. The NRC, therefore, continues to believe that licensee audits of HHS-certified laboratories are an important element of effective FFD programs which are expected to produce consistent, valid results. A revision to § 2.7(n) of Appendix A clarifies that licensees do not have to re-audit those elements of HHS-certified laboratories that are audited by HHS. Instead, licensees should consider auditing these elements and should at least obtain and review the HHS audit reports as part of their audits.

The NRC concurs with the recommendation that wording in Appendix B to Part 50 be added to the final rule and has revised § 26.80(c) accordingly. With respect to the comment on the requirement to audit program elements affected by changes in procedures or personnel, the NRC believes that, if the licensee's quality assurance and quality control procedures effectively evaluate and assure the quality of the FFD program after such changes, then that quality assurance/quality control (QA/QC) process should meet the requirements for an audit of affected program elements.

The NRC also notes that its staff has been informed by senior management at several HHS-certified laboratories that they appreciate the professionalism of licensees' auditors, the quality of their work, and the opportunity to discuss and resolve findings with them. They all indicated that the Part 26 mandated auditing process had improved their laboratories' performance.

39. *Comments About Audit Policy Clarification.*

Commenters raised several specific questions about licensees' responsibility under § 26.80 for auditing contractors, vendors, and HHS-certified laboratories. One commenter asked whether the audit requirements apply to contractors that provide background checks and

psychological evaluations of FFD program personnel and to vendors that supply FFD programs with blind performance specimens and reagents. Two commenters asked whether licensees are allowed to accept other licensees' audits of HHS-certified laboratories in cases where a licensee is required to audit a newly contracted HHS-certified laboratory after its previous HHS-certified laboratory loses its certification. One commenter asked whether it is acceptable for licensees to use contractors to audit their HHS-certified laboratories. Another commenter asked whether the requirement for annual audits of HHS-certified laboratories applies to the "different" HHS-certified laboratories that are to be used for testing in appeals. Lastly, one commenter asked if the requirement for annual audits of HHS-certified laboratories can be focused on only those program areas that fall outside the HHS certification process.

NRC response: The rule requires that contractors and vendors that provide services to implement FFD program elements must be audited. Vendors performing background checks and psychological evaluations of FFD program personnel are not covered by the auditing requirements since they are "Access Authorization" program elements rather than FFD program elements. However, the audit requirement would apply if these vendors have a FFD program that has been reviewed and accepted by the licensee under § 26.23(a). The rule does not require licensees to audit manufacturers of blind performance specimens and reagents because these are "commercially available" supplies and not FFD services. However, the materials these vendors provide must be monitored to assure their accuracy and reliability.

A revision to § 2.7(n) of Appendix A is intended to allow a licensee to accept, in the interim, another licensee's audit of an HHS-certified laboratory when the licensee's own HHS-certified laboratory loses its certification, until the licensee can perform its own audit. This revision is not intended to remove the requirement that the licensee audit the newly contracted HHS-certified laboratory but to provide flexibility for continuous coverage until the licensee can complete the audit. This audit must be accomplished within three months.

In response to the question regarding use of contractors to audit HHS-certified laboratories, it is appropriate to use contractors as long as they have the specific skills needed to conduct such audits. The NRC recognizes that the auditing of some aspects of licensees' FFD programs, especially testing laboratories, requires unique skills which may be available only through consultants or contractors. The licensee, however, remains responsible for the quality and completeness of audit activities.

The requirement for annual audits of HHS-certified laboratories does not apply to the "different" HHS-certified laboratories that may be selected by workers for testing their split specimens. When auditing their HHS-certified laboratories, licensees may review the HHS certification documentation in lieu of an independent audit of the areas covered by the certification program inspections. Licensees are reminded that the use of more stringent cut-off levels, testing for additional drugs, specimen validity determinations, testing of blood, and many other testing requirements of licensees' programs are not covered by the HHS certification process.

A discussion on program performance indicators, which are used to determine the scope and depth of additional audit activities required by §26.80, may be found above under other specific NRC questions.

40. Comments About Implementation of the Revised Rule.

Several commenters generally favored the proposed rule changes, noting that the changes would enhance the clarity, effectiveness, efficiency, and integrity of the rule and improve the general administration of the NRC's FFD program. Many commenters expected that the proposed rule revisions would create significant cost savings and reduce regulatory burden. However, some commenters also stated that the NRC had not met the objectives of the proposed rule changes to reduce cost of rule implementation, provide program enhancement, and continue to protect public health and safety in the most efficient and effective way. They also thought that certain proposed changes would be difficult to implement and would be so complicated that they would not achieve the desired reductions in burden.

These commenters believed that the effects of the proposed rule revisions could be achieved by other means such as by development of regulatory or industry sponsored guidance.

NRC response: After considering the alternative approaches suggested by some commenters, the NRC has concluded that rulemaking is the only effective vehicle for making these changes. Rule change is favored because clear regulatory requirements eliminate interpretive debates. Clear public policy is frequently needed to address legal challenges, ensure that individual rights are protected, and assure that State and local restrictions will not hinder the stringent drug and alcohol testing needed to protect public health and safety. Clear public policy in this area also facilitates collective bargaining. These points were discussed in more detail in the May 9, 1996, Federal Register notice on the proposed rulemaking at 61 FR 21106.

In response to the comments regarding increases in burden, the NRC reviewed the proposed rule revisions and made some changes to reduce potentially complicated processes. In so doing, the NRC noted that several commenters' examples of how the wording of the final rule would have to be implemented introduced complications not suggested by the proposed revisions. In these cases, the NRC has provided clarification of the intent of the revision.

41. *Comments About Backfit.*

The backfitting discussion in the SOC for the proposed rule, 61 FR 21105 (May 9, 1996), divided the proposed changes to Part 26 into three categories: (i) changes necessary to conform with HHS standards, (ii) changes representing reduction in licensee burden, and (iii) other worthwhile changes. Public comment was specifically requested on whether the changes in the proposed rule, considered individually or collectively, constitute a substantial increase in safety and if not, whether the rule should nevertheless be adopted by the Commission. In particular, the SOC requested comment on whether the rule's cumulative effect is to reduce licensee burden, consistent with the position that the Backfit Rule does not apply to relaxations in regulatory requirements. The SOC also requested comment on whether the rule could be adopted if there was no objection from those subject to the rule. *Id.* at 21128-29.

Twelve organizations provided comments on backfitting issues (comments were also made by an NRC employee; the rulemaking addresses those comments as if they were made by a private citizen). The comments can be summarized as follows: (1) most commenters thought the proposed revisions would not create a substantial increase in the overall protection of public health and safety, and (2) several commenters recommended that the NRC should segregate those revisions that would create reductions in requirements from those that would impose new requirements and immediately proceed with rulemaking for those rule revisions that would either reduce licensee burden or result in only minor administrative changes. Commenters also recommended that the proposed revisions that would create new requirements should be withdrawn from this rulemaking and, if still considered desirable by the NRC, should be processed for separate promulgation with appropriate backfit justification. NEI acknowledged that most of the proposed rule revisions would create only minor program adjustments, many of which will increase program effectiveness and efficiency and decrease licensee burden. However, NEI also cited several revisions that should require backfit justification because it believed the revisions would increase licensee burden or that additional reduction in burden should be provided.

After consideration of the public comments on both the desirability of the proposed changes and the backfitting issues, the Commission has decided that there was sufficient

adverse comment on some of the changes that the proposed rule could not be promulgated on the basis of “non-objection” by affected parties. Detailed descriptions and analysis of public comments on individual changes in the final FFD rule are set forth in “Fitness for Duty in the Nuclear Industry: Responses to the 1996 Public Comments.” The Commission’s overall backfitting discussion is set forth below in “Backfit Analysis.”

Summary of Changes From Proposed Rule Revisions

A listing of the modifications made in response to public comments that caused the final rule to differ from the proposed rule is provided below. Minor conforming and administrative modifications are not listed.

§ 26.2(a)(4) — Scope

Section 26.2(a)(4) has been revised to more specifically explain what types of FFD program personnel are included within the rule’s scope. This revision now limits application of the rule to personnel who 1) can link test results to the people who have been tested, and 2) have that information before determination of a FFD policy violation. Also, as compared to the originally proposed revision, the adopted revision adds those who make medical and management determinations of fitness and deletes those who recommend removal or return-to-work decisions.

§ 26.2(e) — Scope

Section 26.2(a) of the current rule requires all licensees authorized to operate a nuclear power reactor to implement an FFD program. Until the 1996 revisions to 10 CFR 50.82, licensees in the process of decommissioning still held a Part 50 license which authorized them to operate the reactor. Accordingly, such licensees were required to maintain an FFD program. When 10 CFR 50.82 was adopted, it removed the authority for a licensee to operate the reactor once the licensee certified that it had permanently removed fuel from the reactor vessel and had permanently ceased operations. A conforming amendment to Section 26.2 was not made to require the licensee to continue the FFD program at the decommissioning plant. A new section 26.2(e) was included in the rule to allow the scope of FFD programs to be reduced for facilities that are being decommissioned as deemed appropriate by the NRC.

Upon reconsideration, the staff believes that the issue of FFD applicability to decommissioning plants should not be resolved in this FFD rulemaking. Rather, the issue of FFD applicability should be resolved as part of decommissioning regulatory improvement initiative under which the staff will reassess the technical and regulatory bases for applicability of the Commission’s 10 CFR Part 50 regulations for operating nuclear power plants. Therefore, the Staff has withdrawn this proposed revision.

§ 26.2(f) — Scope

Section 26.2(f) allows persons performing Part 26 activities who are covered by a program regulated by another Federal agency or State to be covered by only those elements of a licensee’s FFD program that are not included in the Federal agency or State program. As originally proposed, this revision would have required that the Federal agency or State program meet the “general performance objectives of the rule” to be acceptable as an alternative to the licensee’s NRC-mandated FFD program. This section, as revised, now allows employees performing Part 26 activities to be covered by another Federal agency or State program as long as the employees are subject to pre-access (or pre-employment), random, and for-cause urine

testing for the drugs specified in the HHS Mandatory Guidelines, and breath testing for alcohol, at or below NRC mandated cut-off levels; have their urine specimens tested at a laboratory certified by HHS, the College of American Pathologists or other comparable certification program; have awareness training in specified subjects; and have access to an impartial and objective procedure for appealing any findings of a FFD violation. Provisions for notification of the licensee(s) granting unescorted access of any FFD violation by the testing agency or organization must be in place.

§ 26.3 — Definitions: Abuse of Legal Drugs

The definition of “abuse of legal drugs” has been revised to clarify that legal and employment actions against an employee for the use of legal drugs are to be considered presumptive of the abuse of legal drugs rather than as evidence of the existence of a health and safety hazard.

§ 26.3 — Definitions: Aliquot

The definition of "aliquot" has been modified by adding language designed to make it clearer that aliquot is a representative sample of a specimen and can be used for retesting.

§ 26.3 — Definitions: Behavioral Observation

A definition of "behavioral observation" has been added to clarify the role of supervisors in monitoring the behavior of workers under their oversight.

§ 26.3 — Definitions: Blood Alcohol Concentration (BAC)

This term was moved to this section from Section 1.2 of Appendix A because it first appears in the main body of the rule.

§ 26.3 — Definitions: Confirmed Positive Test

The term "confirmed positive test" has been modified to eliminate differing interpretations and ambiguities in the current wording.

§ 26.3 — Definitions: Custody-and-Control Form

A definition of "custody-and-control form" has been added to clarify not only the definition of the term but also to specify which licensees can use this form.

§ 26.3 — Definitions: Followup Testing

This term was deleted because it is fully defined in the text of the rule.

§ 26.3 — Definitions: HHS-Certified Laboratory

This term was moved to this section from Section 1.2 of Appendix A because it first appears in the main body of the rule.

§ 26.3 — Definitions: History of Substance Abuse

A definition of “history of substance abuse” has been added. It is a compendium of the items contained in § 26.27(a)(1).

§ 26.3 — Definitions: Initial or Screening Tests

This term has been replaced by the term "screening test" in the interest of clarity.

§ 26.3 — Definitions: Laboratory Confirmed Positive

The term "laboratory confirmed positive" has been added to refer to the positive outcome of a gas chromatography/mass spectrometry (GC/MS) test. These tests are reviewed by the MRO to determine if they show a violation of the FFD policy or if there is a medical explanation for the positive result.

§ 26.3 — Definitions: Licensee's Testing Facility

This term was moved to this section from Section 1.2 of Appendix A because it first appears in the main body of the rule.

§ 26.3 — Definitions: Medical Determination of Fitness

This term has been added to clarify the role of the MRO or other licensed physician in determining FFD and provide a standard regarding what constitutes this determination.

§ 26.3 — Definitions: Random Test

This term was deleted because it is fully defined in the text of the rule.

§ 26.3 — Definitions: Screening Test

This term replaces the former terms "initial or screening test" in the interests of clarity.

§ 26.3 — Definitions: Strategic Special Nuclear Material

This term has been added to specify its acronym, that is, SSNM (Strategic Special Nuclear Material).

§ 26.3 — Definitions: Substance Abuse

This term has been added both to define the term and clarify the intent of the rule and to support changes to management actions and sanctions regarding alcohol and other legal drugs and substance abuse.

§ 26.3 — Definitions: Subversion and Subvert the Testing Process

The term "subversion" and "subvert the testing process" have been added to define these terms relative to the intentional causing of a missing or inaccurate drug or alcohol test result at any stage of the testing program, including the process of selection and notification, specimen collection, specimen analysis, testing, and reporting of test results.

§ 26.3 — Definitions: Suitable Inquiry

This term was deleted because it is fully defined in the text of the rule.

§ 26.3 — Definitions: Supervisor

A definition of the term "supervisor" has been added to clarify that supervisors include all personnel with supervisory responsibilities over workers with unescorted access, whether they are onsite or offsite.

§ 26.3 — Definitions: Unconfirmed Positive Test Result

The term being defined has been changed from "unconfirmed positive test result" to "presumptive positive screening test result." No change was made to the definition of the term.

§ 26.10(c) — The Goal of Achieving a Drug-free Workplace: Deleted

The final rule deletes the general performance objective in Section 26.10(c) that FFD programs must have a goal of "achieving a drug-free workplace and a workplace free of the effects of such substances." This performance objective is redundant to existing performance objectives (a) and (b), which more directly relate to the Commission's regulatory purview, *viz.*, assuring that workers are not impaired due to drugs and alcohol while performing their duties. In addition, the term, "drug free" workplace in the deleted performance objective is ambiguous. Taken literally, a "drug-free" workplace could not be a valid NRC regulatory objective, since there are valid reasons for workers using over-the-counter and prescription drugs in the workplace, whereas there is no valid reason for workers using alcohol or illegal drugs in the workplace.

§ 26.20(e) — Declaration of Fitness

The proposed revision to ensure that a declaration of fitness was obtained when a worker was contacted for call in instead of after arriving at the site has been withdrawn.

§ 26.24(a)(2) — Chemical Testing: Testing Workers Upon Return to Duty

Language has been added to make clear the intended flexibility with regard to the exact timing of testing workers returning to the site after being absent from the possibility of being tested. The rule permits testing at the earliest reasonable and practical opportunity, without advance notification to the worker.

§ 26.24(a)(3) — Chemical Testing: Delete "Attempts to Subvert" from For-Cause Testing

The phrase "attempts to subvert the testing process" has been removed as a reason to require testing for cause.

§ 26.24(a)(3) — Chemical Testing: Time Limits for For-Cause Testing

Language has been added to provide flexibility regarding time limits in for-cause testing. Revisions have also been made to assure that a positive result of a for-cause test that was not conducted within the time period specified in the rule would still be considered a valid test result when the unusual circumstances that caused the delay are documented. Additional changes to this section would make it clear that both managers and medical personnel need to evaluate fitness.

§ 26.24(a)(3)(ii) — Chemical Testing: Medical Determination For Negative For-Cause Test

The Commission has decided not to adopt the requirement that a medical determination of fitness be performed to evaluate employees who test negative in a for-cause test. Instead, only an appropriate manager need make a determination of fitness.

§ 26.24(a)(4) — Return-to-Duty Testing

This section has been clarified by incorporating the provisions of § 26.27(b)(4) to make explicit that all people to whom unescorted access is reinstated under § 26.27(b)(4) must be subject to unannounced and unpredictable testing. In addition, this section has been modified to clarify the current conditions under which licensees can reinstate unescorted access following a first or second violation of an FFD policy. Section 26.24(a)(4)(ii) has been changed to assure that return-to-duty testing requirements include employees whose access has been removed for a violation of FFD policy involving subversion or attempted subversion of the testing process.

§ 26.24(h) — Chemical Testing: Extrapolation

The requirement for use of extrapolation of alcohol testing results has been replaced with a set requirement based on a standard scale so that a blood alcohol concentration of 0.04 percent or greater upon arrival, 0.03 percent or greater after one hour on duty, or 0.02 percent or greater after two or more hours on duty would be a violation of a licensee's FFD policy.

§ 26.27(a) — Management Actions and Sanctions: Suitable Inquiry

The suitable inquiry requirements have been modified to increase consistency with related access authorization requirements of 10 CFR 73.56, particularly with respect to actions that must be completed before temporary unescorted access may be granted.

§ 26.27(b)(3) — Management Actions and Sanctions: Behavioral Observation During Assessment Period

Language has been added to clarify that requirements for behavioral observation during an assessment period following the first FFD violation apply only to workers still under licensee employ.

§ 26.27(b)(3), (4), (5), and (6) — Sanctions For Alcohol Abuse

The proposed revision that would mandate sanctions for alcohol abuse have been adopted.

§ 26.71(b) and (c) — Recordkeeping Requirements: Permanent Retention of Some Records

Section 26.71(b) has been revised to clarify records retention requirements for documentation that supports a determination that an FFD policy has been violated. Section 26.71(c) has been revised to clarify that documentation pertaining to determinations of FFD policy violations that result in revocation of authorization to perform activities within the scope of Part 26 must be permanently retained. Related changes to § 26.27(b)(3), (b)(4), (b)(5), and (c) have been made to change "removal" or "denial" to "revoked."

§ 26.73(a)(3) — Reporting Requirements: FFD Program Integrity

The requirement to report FFD program personnel violations has been revised to further clarify the NRC's concern for the integrity of FFD program personnel and the integrity of the FFD program itself.

§ 26.80 — Audits

The section has been revised to make it clear that licensees are to take corrective action in response to audit findings. The revision clarifies that licensees are "responsible for determining the appropriate frequency, scope, and depth of auditing activities within the 3-year period based on review of program performance indicators such as the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, previous audit findings, and industry lessons learned." These changes will promote performance-based rather than compliance-based audit activities. The audit program will be conducted so that all programs elements are adequately covered at least once during the 3-year period. This change further clarifies that programs must be audited following a significant change in personnel, procedures, or equipment as soon as reasonably practicable but no later than 12 months after the changes. The NRC recognizes that FFD is an evolving discipline and new issues and problems will continue to arise. Turnover of FFD program personnel and contracted services personnel, such as persons involved in collecting specimens, conducting MRO

reviews, and providing EAP services exacerbates this concern. Licensee audits have identified problems that were associated in some way with personnel changes, such as new personnel not understanding their duties or procedures, the implications of actions that they took, did not take, or changes in processes. The purpose of these focused audits will be to ensure that changes in personnel, procedures, or equipment do not adversely affect the operation of the particular program element or function in question. In addition, § 26.80(c) is amended to clarify that the audit report should identify conditions adverse to the proper performance of the FFD program, the cause of the condition, and to recommend corrective actions. The amended language requires that management review, follow-up actions, and re-audit of deficient areas must also occur. Accordingly, this audit requirement ensures that whatever programmatic problems that may result from significant changes in personnel, procedures, or equipment are detected and corrected on a timely basis.

Pursuant to 10 CFR 26.80(a), licensees must still audit contractor-managed HHS-certified laboratories annually, as described in Section 2.7(n) of the Appendix to Part 26. Licensee audits of the HHS-certified laboratories continue to find problems related to turnover and new personnel. In one case, a licensee's auditors had found sufficient problems to issue a stop-work order. The laboratory subsequently lost its HHS certification. Therefore, based on experiences gained to date, the NRC will continue to require that licensees audit the quality of contractor- or vendor-performed program elements at least annually, as described in 10 CFR 26.80(a), particularly when these activities are provided off site or are not under the direct, daily supervision of the licensee.

Petition for Rulemaking Filed by Virginia Power

This final rule also grants a petition for rulemaking (PRM) filed on December 30, 1993 by Virginia Power to change the audit frequency of FFD programs. In PRM-26-1, the NRC was requested to amend 10 CFR 26.80(a) to require licensees subject to Part 26 to audit their FFD programs every 24 months. Because PRM-26-1 qualified for special handling, as specified in 10 CFR 2.802(e), publication of the docketing of PRM 26-1 was not required. Instead, public comments on PRM 26-1 were requested for the first time, as allowed by 10 CFR 2.802(e), upon publication of the proposed FFD rule on May 9, 1996 (61 FR 21105, 21118). In response to PRM 26-1, § 26.80(a) has been clarified to require that licensees conduct program audits as needed "but no less frequently than every 36 months."

Appendix A, Section 2.1(b) — Testing for Any Substance Suspected of Having Been Abused

The section has been revised to permit licensees to test during for-cause testing for any substance that an employee is suspected of having abused. This section has also been revised to add return-to-duty testing after removals from access under § 26.27(b) or (c) and any test of an employee who is in a follow-up testing program (including random tests) as situations in which licensees can test for illegal drugs or consider any detected drugs or metabolites when determining appropriate disciplinary action.

Appendix A, Section 2.4(f) — Specimen Collection Procedures: Privacy

Wording has been added to § 2.4(f)(1) and (3) to indicate that a questionable specimen that has been examined under the special processing required by § 2.7(e) of Appendix A, and has been determined by an MRO as not having indicated a violation of FFD policy, would not constitute a reason to believe that alteration or substitution of a specimen has occurred.

(Therefore, the specimen donor's subsequent specimens would not be obtained in observed collections.) Also § 2.4(f)(2) has been revised to specify the acceptable variation between specimen temperature and an individual's oral temperature.

Appendix A, Section 2.4(g)(11) — Specimen Collection Procedures: Partial Specimens

Language that specified that partial specimens are to be combined has been replaced with wording that specifies that partial specimens are to be sent to the testing laboratory separately.

Appendix A, Section 2.4(g)(13) and (15): Specimen Collection Procedures: Narrower Temperature Range

Upon reconsideration, the Commission has decided not to adopt a narrower temperature range, and retains the existing temperature range (32.5°-37.7 °C/90.5°-99.8°F) for collected urine specimens.

Appendix A, Section 2.4(i) — Specimen Collection Procedures: Specimen Degradation

The section has been revised to provide flexibility by requiring licensees to take appropriate and prudent actions to minimize false negative results from specimen degradation. The revision also recognizes the possibility that unusual circumstances may prevent specimens being sent to the testing laboratory or subjected to screening testing within the prescribed period. The proposed requirements concerning the timeliness of the shipment and refrigeration have been retained as a goal.

Appendix A, Section 2.7(e) — Laboratory and Testing Facility Analysis Procedures: Validity and LOD Testing

Requirements for specimen validity testing and level of detection (LOD) testing for suspect specimens have been revised to clarify that: (1) specimens that are determined to not be consistent with a valid specimen at the licensee's testing facility should not be screen tested at the licensee testing facility. Instead, they should be sent to the HHS-certified laboratory for processing. (2) Screen testing will include comparison of the screening test results with the acceptable range of negative screening control responses. (3) Those specimens that have screening responses that are greater than the negative control responses must be tested using GC/MS at the laboratory's LOD. (4) MROs would be directed to review negative screening results from special processing and, if there is reason to believe that any instance of dilution is the result of a subversion attempt, that specimen would also be subject to GC/MS testing at LOD. The section is an adaptation of laboratory procedures recommended by HHS under its National Laboratory Certification Program Document #35.

Appendix A, Section 2.7(f)(1) — Laboratory and Testing Facility Analysis Procedures: Non-Instrumented Testing

The section has been changed to specifically prohibit the use of non-instrumented testing devices. The NRC will not allow these devices to be used until HHS has completed its review, finds them acceptable for use in Federally regulated programs, and provides guidelines.

Appendix A, Section 2.7(h)(1) — Laboratory and Testing Facility Analysis Procedures: HHS-Certified Laboratory Reporting Time

The proposed one-day reduction in the period within which HHS-certified laboratories must report test results to licensees (from five to four working days) has been removed.

Appendix A, Section 2.7(h)(6) — Laboratory and Testing Facility Analysis Procedures: Monthly Statistical Summary

This section has been modified to require the HHS-certified laboratory and the licensee's testing facility to provide to the licensee official responsible for coordination of the FFD program a monthly statistical summary of urinalysis and blood testing.

Appendix A, Section 2.7(k) — Laboratory and Testing Facility Analysis Procedures: Split Specimens

This section has been revised to clearly state that, if a split specimen test result fails to reconfirm the test result on a primary specimen, the MRO continues to have the discretionary authority to determine whether or not a FFD policy violation has occurred. Also, new wording has been added to this section to require the MRO to consider the conflicting results between the tests on the primary and split specimen plus any other relevant information in making the FFD policy violation decision. Revisions to § 2.7(b) of Appendix A also make clear that any failure of a split to confirm the results on the primary specimen must be investigated as required by § 2.8(f) of Appendix A.

Four other changes to this section were also made. One removes the specification that the specimen be split in half, because the specimen is now split into two unequal parts. Another provides three weekdays (not to include holidays) for the split specimen to be forwarded rather than having to be forwarded "that day." The third clarifies that split sample can be tested only at the employee's request. The fourth removes the 72-hour minimum period that must be provided the individual for making a "timely" request that the split specimen be tested.

Appendix A, Section 2.8(e)(3) — Quality Assurance and Quality Control: Controls for Dilute Specimens

The requirement for diluting blind performance test specimens and spiking them at 60 percent of the cut-off level has been revised to require that the adulterated or diluted blind performance specimens be spiked to between 60 and 80 percent of the licensee's cut-off level.

Appendix A, Section 2.9(c) — MRO Verification of Positive Test Results

The section has been revised to expand its coverage to all FFD policy violations, to authorize MROs to declare a FFD policy violation when the employee does not report to the MRO after notification to report, and to allow the MRO to rescind a declaration of FFD policy violation if the employee reports to the MRO after being unavailable for an extended period and has a legitimate explanation for the positive test result and failure to report promptly.

Appendix A, Section 2.9(d) — Reporting and Review of Results: Clinical Evidence

Proposed wording has been revised to remove "evidence of a significant lack of reliability and trustworthiness on the part of the worker" as clinical evidence of opiate abuse and adds admission of non-prescribed opiate use as an example of such clinical evidence.

Appendix A, Section 2.9(h) — Reporting and Review of Results: MRO Determination of Result Scientifically Insufficient

This section has been modified to add that "for a minimum of 3 years" the licensee shall maintain records that summarize any negative findings based on scientific insufficiency and shall make them available to the NRC on request.

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, P.L. 104-113, requires that Federal agencies use technical standards developed by or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is revising the regulations that establish its Fitness-For-Duty program. There are no voluntary consensus standards with respect to the subject of Fitness-For-Duty as established in this rulemaking. Therefore, the provisions of the Act do not apply to this rulemaking.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(2). Therefore, the NRC has not prepared an environmental impact statement nor an environmental assessment for this final rule.

Paperwork Reduction Act

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget (OMB) approval number 3150-0146.

The final rule will relax existing information collection requirements and will contain new information collections. The overall effect will reduce existing information collection requirements, and the overall public burden of this collection of information is expected to be decreased by approximately 9,420 hours annually (131 hours per licensee). This estimate includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for reducing the burden, to the Records Management Branch (T-6E6), U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0146), Office of Management and Budget, Washington, D.C. 20503.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

The Commission has prepared a regulatory analysis for this regulation. The analysis examines the benefits, cost savings, and the costs of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW (lower level), Washington, DC. Single copies of the analysis may be obtained from Dr. Garmon West, Jr., Division of Inspection Program Management, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-1044.

Regulatory Flexibility Act Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule affects only the licensing and operation of nuclear power plants and activities associated with the possession of transportation of Category I material. The companies that own these plants do not fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards adopted by the NRC on April 11, 1995; 60 FR 1834 (10 CFR 2.810).

Backfit Analysis

The Commission has evaluated the changes in the final FFD Rule in accordance with the Backfit Rule, 10 CFR § 50.109, and has decided to adopt with some modification most of the provisions in the proposed FFD Rule.

The Commission’s compliance with the Backfit Rule for this rulemaking differs from its usual practice, in that the Commission has evaluated the individual provisions of the final FFD Rule for their individual backfitting implications as well as performed an overall evaluation of the rule. Most rulemakings directed at nuclear power plants have amended a single rule or regulatory provision within a rule, e.g., the change to paragraph (a)(4) of the Maintenance Rule, 64 FR 72001, December 23, 1999. By contrast, the final FFD Rule represents an overall re-evaluation and refining of Part 26 as a whole. Although these changes are focused on five key areas (identified below under section “B. Consideration of the FFD Rule as an Integrated Rule,” and discussed in more detail in the Regulatory Analysis for the Final FFD Rule), it is possible that aggregation of the rule’s changes when applying the Backfit Rule could obscure the backfitting implications of a comprehensive rulemaking with multiple provisions. For example, a determination that the FFD Rule *overall* represents a “compliance exception” would not identify the benefits and costs of one or more changes that could have significant resource impacts (costs or savings) on licensees. Similarly, aggregation of the costs and benefits of all changes could potentially obscure the cost contribution of a single change (or a small set of changes) whose safety benefits in context are limited and perhaps unjustified. Therefore, to gain a better understanding of the backfitting implications (including benefits and costs as appropriate) of specific FFD changes as well as the benefits and costs attributable to the FFD Rule overall, the Commission has evaluated the FFD Rule using two different approaches. Under the first approach, the Commission evaluated each individual rulemaking change¹ for its backfitting

¹By “change,” the Commission means a single regulatory concept whose expression as a requirement may be reflected in one or more regulatory provisions in Part 26. In some cases, a change may affect only a single provision in the rule being changed; in other cases, two or more provisions may have to be changed. For example, the proposed change to require that partial urine samples must not be combined, but be packaged separately, see “Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-For-Duty Rule (10 CFR Part 26) (“Backfit Analysis”), pp. 26-27, is embodied in a single regulatory provision: proposed Section 2.4(g)(11) to 10 CFR Part 26, Appendix A. By contrast, the proposed change to allow licensees to test for 6-acetylmorphine (6-AM) only when the morphine concentration found in confirmatory

implications independent of any other change, by first assessing whether the change constitutes a backfit as defined in the Backfit Rule, and if so whether one of the exceptions in paragraph (a)(4)(i) through (iii) applies to that change. If a change is not screened out as an exception, then it is analyzed to determine if the change represents a substantial increase in protection to public health and safety, and whether the cost of the change is justified in light of the increased protection provided by the backfit (the “cost-justified substantial increase” threshold of the Backfit Rule). Under the second approach, the Commission evaluated the FFD Rule as an integrated rule. Thus, the Commission considered the overall effect of the FFD Rule in determining whether the rule represents a backfit, whether the rule as a whole falls within one of the three exceptions, and whether in the aggregate the rule passes the “cost-justified substantial increase” threshold.

The Commission believes it has sufficient flexibility under the Backfit Rule to perform the backfitting evaluation using either approach or both approaches simultaneously, depending on the nature of the rule and the Commission’s determination on which approach provides the best insight into the backfitting implications of a rulemaking. The Commission recognizes that the definition of a backfit² as well as the substantive requirement for performing the backfit analysis under paragraph (a)(3)³ is couched in the singular form, which could be interpreted to require the “cost-justified substantial increase” finding to be made for each individual changed provision in a rulemaking. Nonetheless, the Commission believes that an alternate interpretation is equally acceptable, *viz.*, the Commission understood that the several requirements embodied within a single rulemaking are usually directed at a single subject matter, and therefore the backfit analysis should evaluate the overall costs and benefits attributable to the requirements proposed for addressing that subject matter. Conceptualized in this fashion, it is natural to characterize the whole regulatory action “the backfit” in singular terms. The statements of considerations (SOCs) for the 1985 Rule and 1988 amendment are not inconsistent with this interpretation. See 50 FR 38097 (September 20, 1985), 53 FR 20603 (June 6, 1988). The Commission’s interpretation of the Backfit Rule is also unconstrained by any statute, since the restrictions in the Backfit Rule are not mandated by statute, but represent self-imposed restrictions voluntarily adopted by the Commission to address nuclear power plant licensees’ desire for regulatory stability⁴. Thus, the Commission has considerable flexibility in applying the Backfit Rule, limited only by the well-established confines of lawful agency action under the

testing exceeds 2,000 ng/ml, see Backfit Analysis, pp. 33-34, is embodied in two regulatory provisions: Section 2.7(g)(2) and (5) to Part 26, Appendix A.

²10 CFR 50.109(a)(1) defines a backfit as, *inter alia*, a “modification” of a plant or its procedures resulting from a “a new or amended *provision* in the Commission’s rules....”(emphasis added)

³10 CFR 50.109(a)(3) provides that a backfit may be imposed only if the Commission determines that there is a substantial increase in overall protection “to be derived from the *backfit*....”(emphasis added)

⁴By contrast, the Commission has adopted other procedural requirements that are specifically controlled by statute, e.g., the “Sholly” requirements in 10 CFR 50.91 and 50.92, which are specifically authorized under Section 189 of the Atomic Energy Act of 1954, as amended. In these cases, the Commission’s interpretation of its regulations is constrained by the language of the underlying statute.

Administrative Procedure Act (APA). In fact, the Commission's practice has been to aggregate the costs and benefits of rulemakings as a whole in determining whether a rulemaking meets the "cost-justified substantial increase" test of the Backfit Rule. Finally, the Commission points out that its interpretation does not frustrate the objectives for which the Commission originally adopted the Backfit Rule. The Backfit Rule was intended to achieve "regulatory stability" by requiring that the Commission perform a careful analysis of certain proposed changes, and adopting a substantive threshold for imposing backfits, the "cost-justified substantial increase" standard. Both requirements remain undisturbed by the Commission's interpretation.

Analysis of Substantial Increase in Protection, and Costs Attributable to FFD Rule

A. Individual Treatment of Final Rule's Changes

The Commission has individually evaluated each of the proposed changes in the final FFD Rule for its individual backfitting implications. These evaluations are documented in "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26)" ("FFD Backfit Application Analysis"), as well as the "Regulatory Analysis of Final Rulemaking Part 26 - Fitness-For-Duty Programs" ("Regulatory Analysis"), which are available for inspection and copying for a fee at the NRC Public Document Room. As discussed in greater detail in the FFD Backfit Application Analysis, the Commission concludes that the changes in the final rule fall into one or more of the following categories with respect to backfitting:

- (1) Clarifications. Several revisions will clarify current requirements to assure consistent understanding and implementation of the Commission's original intent for these requirements. Without changing the requirements stated in these sections, these revisions would remove the ambiguities that produced the licensee's uncertainty. Revisions that do not change existing requirements are not considered to be backfits as defined in section 50.109(a)(1), and are not subject to the Backfit Rule's requirements.
- (2) Administrative matters. A few revisions make minor administrative changes, such as correcting typographic errors, correcting inconsistencies, relocating requirements from one section to another, and combining existing requirements into a single section. Administrative changes are not subject to the Backfit Rule requirements.
- (3) Permissive relaxations. Several changes permit, but do not require, relaxations of current requirements (i.e., licensees are free to either comply with current requirements or adopt the relaxed requirements as an alternative). Changes that provide permissive relaxations of current requirements are not considered to be backfits as defined in section 50.109(a)(1), and are not subject to the Backfit Rule's requirements.
- (4) Information collection and reporting requirements. A few changes amend existing information collection and reporting requirements, or impose new information collection and reporting requirements. The Backfit Rule does not apply to information collection and reporting requirements. Therefore a backfit analysis is not required. However, the Commission prepared a September 28, 1998, "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-For-Duty Rule (10 CFR Part 26)." This document discusses each new or amended information collection and reporting requirement, by summarizing the purpose and intended use

of the information proposed to be collected, and identifying the projected costs of the information collection and reporting requirement. This constitutes a disciplined process for evaluating the potential benefits and impacts of the information collection and reporting requirements in the final FFD Rule. The Commission concludes that the objective underlying the adoption of the Backfit Rule, "that regulatory impacts are assessed under established criteria in a disciplined process," is met with respect to the information collection and reporting requirements in the final FFD Rule.

(5) Compliance exceptions. Several changes are necessary to bring licensees into compliance with existing Commission requirements or the Commission's clearly stated intent in promulgating the requirement. In addition, some of the changes modify current requirements where there is evidence that the current version of the standard is not achieving the purpose that the Commission had when it originally promulgated the rule. Pursuant to Section 50.109(a)(4)(i), a backfit analysis need not be prepared.

(6) Worthwhile changes to be adopted as Backfit Rule Exceptions. Some of the changes are backfits, but they neither fall into one of the exceptions in Section 50.109(a)(4)(i) through (iii), nor do they, considered individually, constitute a "substantial increase" in protection to public health and safety whose cost is justified in light of the increase in protection.

Consistent with a June 30, 1993 Staff Requirements Memorandum (SRM) that exceptions to the Backfit Rule be promulgated only after notice and opportunity for public comment⁵, the statement of considerations (SOC) for the proposed FFD Rule stated that the Commission was considering adopting provisions of the proposed rule as "worthwhile improvements," and invited public comments on this proposal. See 61 FR at 21129 (first and second columns). After consideration of the public comments, the Commission believes that 36 changes can be regarded as "worthwhile improvements" to Part 26 and that the requirements of the Backfit Rule need not be applied to the portion of this rulemaking adopting these changes. The reasons why the 36 changes represent "worthwhile improvements are discussed in detail in the "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26)." The 36 changes are:

⁵The June 30, 1993 SRM said:

Despite the flexibility which the Commission believes inheres in the "substantial increase" standard, there may be proposed rules which, in the staff's opinion, do not meet that standard and should be promulgated mainly for nonsafety reasons. As in the past, the Commission remains willing to consider, on a case-by-case basis, whether such rules should be promulgated as exceptions to the Backfit Rule. However, it is the judgement of the General Counsel that using 10 CFR 50.12 to promulgate such exceptions is not a sound regulatory approach. The Commission therefore concludes that such exceptions should be promulgated only if the proposal not to apply the Backfit Rule to the proposed rulemaking is made the subject of notice and comment.

June 30, 1993 SRM on SECY-93-086 - Backfit Considerations, p. 2.

- (1) *Section 26.2(a)(4): FFD program personnel to be covered by FFD rule.*
- (2) *Section 26.20(a): Off-site involvement with drugs, subversion of the testing process, and refusals to test added. Note: This revision consists of three parts and only the one part requiring FFD policies to address off-site involvement of drugs is recommended to be considered a worthwhile change.*
- (3) *Section 26.23(a)(2): Clarify that persons with a known (to the contractor or vendor) history of substance abuse must not receive assignments to the protected area without the knowledge and consent of the licensee.*
- (4) *Section 26.24(a)(5): Clarify existing testing requirements for persons unavailable for testing for short periods and insure consistency with the access authorization program. Note: This revision consists of three parts and only the one part concerning tests after extended absences is recommended to be considered a worthwhile change.*
- (5) *Section 26.24(a)(5): Require return-to-duty testing after extended absences or denial of access. Note: This revision consists of two parts and only the one part concerning the testing of personnel returning to work after extended absences or after having been denied access under section 26.27(b) is recommended to be considered a worthwhile change.*
- (6) *Section 26.24(f): MRO to report FFD policy violation in writing.*
- (7) *Section 26.24(h): Require that a blood alcohol concentration of 0.04 percent or greater upon arrival, 0.03 percent or greater after one hour on duty, or 0.02 percent or greater after two or more hours on duty would be a violation of a licensee's FFD policy.*
- (8) *Section 26.25: Clarify that EAPs must be designed to achieve early intervention and must ensure confidentiality.*
- (9) *Section 26.27(a): Certain aspects of fitness history to cover a 5 year period.*
- (10) *Section 26.27(b)(1), (3), and (5): Clarification of requirements with respect to access denial, removal, and return to service. Note: This revision consists of two parts, and only the revision to section 26.27(b)(1) concerning who can make return-to-duty decisions is recommended as a worthwhile change.*
- (11) *Section 26.27(b)(3): People suspended must still be covered by behavioral observation, chemical testing, and sanctions for violations.*
- (12) *Section 26.27(c): Clarify that acts of subversion are violations of licensee's FFD policy and result in denial of unescorted access for 3 years and that the specific cause for removal must be provided in response to an inquiry.*
- (13) *Section 26.28: Clarify that the appeals process must be objective and conducted by persons not associated with the FFD program.*

- (14) *Section 26.29(c): Assure provision of copies of records to individuals upon written request.*
- (15) *Section 2.4(f)(1) and 2.4(f) of Appendix A: Current or previous specimen that fails to meet normal standards constitutes a reason to require observed testing and minor clarifying changes.*
- (16) *Section 2.4(g)(4) of Appendix A: Eliminate requirement that tester request list of medications prior to specimen collection.*
- (17) *Section 2.4(g)(11) of Appendix A: Require partial specimens to be shipped separately and not combined.*
- (18) *Section 2.7(c) of Appendix A: Require chilling or testing within one day of arrival at HHS-certified laboratory.*
- (19) *Section 2.7(e) of Appendix A: Conduct special processing of questionable specimens at HHS-certified laboratory (formerly: Test questionable specimens to limit of detection).*
- (20) *Section 2.7(e): Require on-site testers to determine validity of specimens on site.*
- (21) *Section 2.7(f) of Appendix A: Prohibit non-instrumented testing devices.*
- (22) *Section 2.7(g) of Appendix A: Modify the criteria for determining that a specimen is positive for amphetamines.*
- (23) *Section 2.7(g) of Appendix A: Require testing for d and l isomers of amphetamines.*
- (24) *Section 2.7(i) of Appendix A: Specimens associated with subversion to be placed in long-term storage.*
- (25) *Section 2.7(j) of Appendix A: Retesting of adulterated or diluted specimens need only confirm specimen not valid.*
- (26) *Section 2.7(k) of Appendix A: Minimum time for requests by individuals to have split specimen tested at another HHS-certified laboratory.*
- (27) *Section 2.7(p) of Appendix A: Laboratory shall not have a conflict of interest with licensee's MRO.*
- (28) *Section 2.8(b) of Appendix A: Laboratory results on blind performance specimens must be evaluated and appropriate corrective actions taken.*
- (29) *Section 2.8(e) of Appendix A: Require that blind quality control materials meet standards for preparation, certification, and stability.*
- (30) *Section 2.8(e) of Appendix A: Assure regularity of submission of blind test specimens.*

- (31) *Section 2.8(e) of Appendix A: Adulterate or dilute and spike some blind performance specimens.*
- (32) *Section 2.8(e) of Appendix A: Specify that initial 90-day period for blind performance testing rate applies to all new contracts with HHS-certified laboratories.*
- (33) *Section 2.8(f) of Appendix A: Investigation of testing process errors and inclusion of report of action taken. Note: This revision consists of two parts and only the one part requiring licensees to investigate testing process errors is recommended to be considered a worthwhile change.*
- (34) *Section 2.8(f) of Appendix A: All false positive errors must be reported to NRC. Note: This revision consists of two parts and only the one part requiring the licensee to require the HHS-certified laboratory to take corrective action is recommended to be considered a worthwhile change.*
- (35) *Section 2.9(b) of Appendix A: MROs shall not have a conflict of interest with certified laboratories.*
- (36) *Sections 2.9(f) and (g) of Appendix A: Medical determination of fitness to perform duties defined.*

The Commission is satisfied that the public had fair notice that the Commission was considering adopting proposed changes determined not to meet the “substantial increase” standard. The Commission is also satisfied that its approach is consistent with the Commission’s intent in the June 30, 1993 SRM.⁶

Based upon the evaluations in the FFD Backfit Application Analysis, the Commission finds: (i) no single change in the final FFD Rule will likely impose a disproportionate cost impact on licensees; and (ii) the FFD Rule is not comprised of a single rule change (or relatively small

⁶The SOC for the proposed FFD Rule, after requesting comments on whether the proposed changes, considered as a whole or individually, provide a substantial increase in protection to public health and safety, continued by posing the following question, “If the Commission were unable to conclude...that these changes would provide a substantial increase in overall protection, the further question arises whether the rule should nonetheless go forward. *One* approach to continuation of the rulemaking would be to view the rule as a whole...Alternatively, the question is presented whether...non-objection [by those subject to the new requirements] could be grounds for not applying the backfit rule...Public comment on these *considerations* is specifically invited.” 61 FR at 21129, first and second columns (emphasis added). If the Commission intended to receive comments on only the two listed alternatives, the Commission would not have invited public comment on “these considerations,” but would have limited public comment on “these two alternatives.” Furthermore, nuclear power plant licensees should have been familiar with the June 30, 1993 Commission SRM providing direction to the Staff on “administering the substantial increase standard with the degree of flexibility the Commission originally intended.” That SRM provided specific guidance to the Staff and interested stakeholders with respect to acceptable means of demonstrating that the “substantial increase” standard in the Backfit Rule has been met, and raised the possibility of promulgating rules as “exceptions” to the Backfit Rule.

cluster of rule changes) whose benefits are being used to offset the costs of a large number of rule changes that have little or no safety (or other worthwhile) benefit. The Commission has also determined, based upon the FFD Backfit Application Analysis, that the 36 changes identified above as “worthwhile improvements” each provide significant improvement to the fitness-for-duty regulatory structure of Part 26, and that the cost of each change is not inordinate compared with the reasons for adopting the improvement. Accordingly, the Commission finds that these 36 changes represent “worthwhile improvements” that could be adopted even though they, taken individually, do not provide a substantial increase in protection to public health and safety. Nevertheless the Commission has decided to consider in the aggregate all of the changes in the final FFD Rule, including these 36 worthwhile changes, as an integrated whole.

B. Consideration of the FFD Rule as an Integrated Rulemaking

The Commission has evaluated the final FFD Rule as an integrated rulemaking for backfitting implications. Inasmuch as the changes in the FFD rule are interrelated and deal with a single subject area - FFD programs - the Commission finds that it is appropriate to follow the Commission’s ordinary practice of assessing the backfit implications of these changes as a single, integrated rulemaking.

The Commission has determined that the changes in the FFD rule, considered collectively as an integrated rule, constitute a backfit as defined in 10 CFR § 50.109(a)(1), and that none of the three exceptions in subparagraph (a)(4)(i) through (iii) apply to this rulemaking. Therefore, in accordance with 10 CFR 50.109(a)(3) and (c), the Commission evaluated the FFD Rule to determine if the integrated rule meets the “cost-justified substantial increase” threshold of the Backfit Rule.

In determining whether this threshold is met, the Commission considered in qualitative terms the safety benefits afforded by the FFD Rule’s provisions as documented in both the Regulatory Analysis for the FFD Rule and the FFD Backfit Application Analysis. A qualitative consideration was necessary for several reasons. Quantitative consideration of FFD safety benefits would require that the NRC use a model which relates FFD incapacity to cognitive errors that initiate or contribute to the initiation or undesirable evolution of accidents resulting in offsite releases of radioactivity (and consequent doses) to the general public. The doses would then be converted into dollar amounts using the \$2,000/man-rem dose conversion factor which the NRC has adopted in the Regulatory Analysis Guidelines, NUREG/BR-0058, Revision 2 (November 1995). The NRC has not developed such a model, nor is the NRC aware of the existence of a validated model in the general scientific literature. While it might be possible for the NRC to develop such a model, the cost of preparing and validating such a model would be substantial, and once developed it would have limited applicability to NRC regulatory matters other than fitness-for-duty. Furthermore, development of such a model would require accurate and complete data which show the incidence of errors whose root cause can be tied to worker incapacity or impairment. The NRC does not have such data, nor can the data be easily collected. Accordingly, the Commission decided to evaluate the FFD Rule’s safety benefits in qualitative terms. The overall determination of whether the costs of the FFD Rule are justified in light of the safety benefits afforded by the rule was necessarily qualitative, given that the benefits were assessed in qualitative terms. By contrast, the Commission considered the costs and cost reductions in quantitative terms, as documented in the Regulatory Analysis and the FFD Backfit Application Analysis.

The Commission's analysis considered all of the FFD Rule's provisions, including those changes that considered individually would not be regarded as backfits (e.g., permissive relaxations, information collection requirements), as well as the 36 "worthwhile changes" identified above.⁷ In addition, the Commission considered the nine factors in Section 50.109(c) as follows:

(i) *Statement of the specific objectives that the proposed backfit is designed to achieve.*

The rulemaking constitutes an integrated regulatory initiative directed at a single regulatory matter: fitness-for-duty requirements at nuclear power plants. The purposes of this rulemaking are to: (i) update the Commission's FFD requirements to be consistent with the US Department of Health and Human Services (HHS) Guidelines for FFD testing, with HHS being the lead federal agency for developing substantive FFD testing methodologies and strategies, (ii) adopt corrections, clarifications and improvements to FFD testing for onsite licensee testing - an area which HHS Guidelines do not address; (iii) adopt changes and improvements to FFD programs based upon Commission and industry experience to address historical experience with subversion and test integrity, and (vi) adopt changes and improvements to address issues related to protection of the rights of tested individuals. These objectives are also discussed in the Regulatory Analysis and the FFD Backfit Application Analysis.

(ii) *General description of the activity that would be required by the licensee or applicant in order to complete the backfit.*

In general terms, the final FFD rule would require licensees to modify their procedures for on-site testing, in part to comply with HHS Guidelines, require off-site laboratories to comply with HHS guidelines, perform additional testing in specific circumstances set out in the final rule, and comply with certain procedures intended to protect the rights of tested individuals, while assuring that persons who are impaired and/or are using illegal drugs do not perform safety functions at a nuclear power plant. Detailed discussions of what activities and changes in procedures would be required by the FFD Rule are set forth in the Regulatory Analysis and the FFD Backfit Application Analysis.

⁷When the Commission is assessing whether rulemaking changes *in the aggregate* meet the "cost-justified substantial increase" threshold, it is methodologically correct and appropriate for the Commission to consider the benefits and costs attributable to those changes that, considered in isolation, would not be regarded as backfits, e.g., permissive relaxations from current requirements. The differing manner in which permissive relaxations are treated in an aggregated backfit analysis versus an analysis that evaluates each change individually stems from the fact that the aggregated backfit analysis conceives the backfitting issue differently from the "individual change" analysis. The aggregate backfit analysis is focused on the overall impact of the rule as a whole. The "individual change" analysis is intended to answer the question, for integrated rulemakings consisting of a large number of related changes, whether there is a single change (or group of changes) that entail little benefit but impose substantial costs. Since the analyses are intended to focus on different aspects of the backfitting issue, it is not unexpected that their methodological approaches differ.

- (iii) *Potential change in the risk to the public from the accidental off-site release of radioactive material.*

The rulemaking is intended to provide added assurance that the risk of offsite releases of radioactive material as a result of human error attributable to cognitive impairment from fatigue, and the use of legal and illegal drugs, or because of psychological factors, is acceptably low and consistent with the Commission's Safety Goals. However, the reduction in risk to the public from offsite releases of radioactive materials cannot be quantified, since there is insufficient information and modeling to support such quantification.

- (iv) *Potential impact on radiological exposure of facility employees.*

The rulemaking will provide added assurance that nuclear power plant workers are not subjected to unnecessary radiological exposures either directly as the result of cognitive impairment (e.g., where a worker receives a radiological exposure which is greater than expected because of impairment while performing a work function, including mitigative and/or clean-up activities after an accident), or because cognitive impairment causes an accident leading to a release of radiation, which the worker is then exposed to as the result of mitigative and/or clean-up activities.

- (v) *Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay.*

FFD is primarily programmatic in nature, and does not involve changes to the facility itself; hence there will be no installation or downtime costs associated with implementing the final FFD Rule. The regulatory analysis for the FFD Rule sets forth the Staff's estimate of the initial costs for implementing the major elements of the final FFD rule, and the ongoing costs to the licensees. Since licensee FFD programs are already well established, all costs associated with this rulemaking are expected to be of an incremental nature. The estimated initial, one-time industrywide costs would be \$165,000 for increasing the scope of the rule to include FFD program personnel and for making revisions to policies and procedures to assure compliance with rule changes. The recurring annual cost to implement all other rule changes industrywide would be an estimated \$856,000. Taking into account the estimated one-time industrywide costs of \$165,000 that would be incurred in the first year of rule revision implementation, the present value of the industry's net savings over the twenty year period would be approximately \$284,625,000, assuming a seven percent annual discount rate.

- (vi) *The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements.*

The final FFD rule makes no change with respect to the design of a nuclear power plant. Therefore, the final rulemaking is not expected to have any effect on facility complexity.

The final rule also does not affect the direct procedures for operating the plant. Rather, the changes to Part 26 in the final rule are directed to the ancillary procedures and supporting administrative organization associated with operating the plant. The final rule will require additional testing to be required (e.g., employees who are offsite when selected for testing), as well as changes to FFD program procedures to ensure greater integrity of tests and to reduce tampering and subversion. These qualitative “costs” in terms of increased complexity in FFD procedures are documented in the FFD Backfit Application Analysis. From this assessment, the Commission finds that the added FFD program complexity is not significant and will not substantially impact licensees’ operational practices or result in substantial indirect costs.

- (vii) *The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources.*

The rulemaking is not likely to result in a substantial increase in expenditures of agency resources, since the NRC already is inspecting licensees’ implementation of FFD programs required by Part 26, and the final FFD rule does not contain any substantial expansion of the FFD activities currently required under Part 26. The clarifications and reductions in ambiguous regulatory language are expected to decrease expenditures of NRC resources responding to licensee questions and taking appropriate regulatory action (e.g., issuance of notices of violations, enforcement conferences) because of divergences between NRC and licensee interpretations of Part 26 requirements. Finally, NRC inspection resources may decrease slightly because the range of FFD program activities needed to be inspected may decrease due to the permissive relaxations contained in the final FFD Rule.

- (viii) *The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit.*

The requirements for FFD in Part 26 do not relate to, and are independent of, the facility type, design or age. Therefore, the benefits and costs attributable to the final FFD Rule changes do not vary based upon the facility type, design or age.

- (ix) *Whether the proposed backfit is interim or final and, if interim, the justification for imposing the backfit on an interim basis.*

The backfit is final.

The Commission finds that the FFD Rule, considered in the aggregate, constitutes a substantial increase in protection to public health and safety, by addressing the following five key areas that have been identified by the Staff as posing recurring and in some cases significant problems with respect to the effectiveness, integrity, and efficiency of FFD programs at nuclear power plants: (i) subversion of the detection/testing process to avoid detection; (ii) “regulatory friction,” or the incompatibility/inconsistency/redundancies between NRC requirements for FFD and other guidance or statutory requirements, such as the FFD guidance

developed by HHS, which is the lead federal agency for the development of FFD programs; (iii) ineffective/unnecessary FFD requirements, resulting in unnecessary expenditures of resources by licensees; (iv) ambiguous or insufficiently-precise regulatory language in Part 26, resulting in inconsistent FFD programs and unnecessary expenditures of licensee and NRC resources to resolve inconsistent interpretations of Part 26 requirements; and (v) technical developments improving the accuracy and specificity of drug tests, which could reduce both false positives and false negatives. In addition, the final FFD Rule contains provisions intended to ensure the integrity of the FFD program and protect the rights of tested individuals. These key areas and the issue of protection of the rights of individuals, and the manner in which specific FFD Rule provisions address these areas and issues, are discussed in the Regulatory Analysis and the FFD Backfit Application Analysis. The Commission finds that the integrated changes affecting these five areas represent a substantial increase in protection to public health and safety as discussed below:

(i) subversion of the detection/testing process

The Commission's intent when it first adopted Part 26 was that FFD programs have a high degree of effectiveness such that nuclear power plants would be essentially "drug-free," see (54 FR 24468; June 7, 1989). To that end, the current FFD Rule contains several provisions aimed at preventing subversion. However, as documented in the FFD Backfit Application Analysis, subversion techniques have evolved and grown more sophisticated since the adoption of the anti-subversion provisions of the 1989 rule. The Commission believes that the adoption of the anti-subversion provisions in the final FFD Rule will serve to keep pace with the evolution of subversion techniques, thereby maintaining the level of effectiveness that the Commission originally intended when it adopted the 1989 FFD Rule. Accordingly, the Commission finds that provisions in the final FFD Rule aimed at preventing subversion constitute a substantial increase in protection to public health and safety.

(ii) "regulatory friction"

The 1989 FFD Rule requirements were based upon, and keyed to, the drug testing provisions in the HHS Guidelines. HHS, as the lead Federal agency for the development of FFD programs and drug testing requirements, has periodically revised its Guidelines based upon its review and experience with both Federal and private-sector FFD and drug testing programs. The Commission believes that there is substantial benefit to conforming its regulations to the most recent HHS Guidelines, taking into account the unique characteristics of the nuclear power plant industry which may counsel departures from specific aspects of the HHS Guidelines. As the Commission stated in its June 30, 1993 SRM, conformance with national standards may be a basis for finding substantial increase in protection. In view of the nature of the HHS Guidelines, the Commission believes that the FFD changes to conform Part 26 to the HHS Guidelines does represent such an instance.

(iii) ineffective/unnecessary FFD requirements

A significant number of the FFD Rule's changes remove requirements from Part 26 which implementation data show are either unnecessary or ineffective in achieving the intended objective of the requirement. Removing such requirements simplifies the FFD program and permits licensees to focus their attention on Part 26 requirements that have a more direct

impact on FFD program effectiveness. Accordingly, the Commission regards these provisions as providing a substantial increase in protection to public health and safety.

(iv) ambiguous or insufficiently-precise regulatory language in Part 26

A substantial number of provisions in the final FFD Rule are intended to clarify current Part 26 requirements which use ambiguous or imprecise language. These changes are based upon the NRC Staff's experience with the implementation of Part 26, which has included situations where the licensee's interpretation resulted in increased opportunities for subversion, decreased assurance of FFD test integrity, and ineffective corrective action in response to confirmed positive results. Accordingly, the Commission finds that these provisions, which are intended to correct the deficiencies attributable to ambiguous or imprecise regulatory language, provide a substantial increase in protection.

(v) technical developments

A number of the final FFD Rule's provisions are intended to reflect the technological improvement in testing methodologies, which improves the capability to narrow in on specific drug metabolites and isomers that are indicative of illegal drugs, and which have increased sensitivity permitting detection at lower levels. Such improvements can reduce false positives, thereby reducing the adverse effects to individuals and can reduce licensee resources currently expended on validating false positives. The improvements also have the capability to reduce false negatives, thus providing greater assurance that persons who have reduced cognitive functions due to illegal drug use are detected and prevented from performing safety-related work. The Commission finds that these provisions constitute a substantial increase in protection to public health and safety.

(vi) FFD program integrity and protection of individual rights

Several of the final FFD Rule's provisions are intended to ensure that the FFD program requirements are implemented fairly by the licensee, and that individuals with significant responsibilities are not inappropriately influenced when performing their duties. Other provisions are intended to protect the rights of tested workers, by providing a fair opportunity to address any findings of illegal drug use. The Commission regards these changes collectively as providing a substantial increase in protection to public health and safety. A successful FFD program, and more generally a positive regulatory environment, depends in part upon the perception by nuclear power plant workers that the NRC's regulatory requirements and their implementation by licensees are fair and appropriately tailored. Workers who do not believe that NRC requirements are fair may be less likely to regard other NRC requirements, or licensee procedures which implement NRC requirements, as justified and may be more likely to disregard them.

Adoption of the provisions in the FFD Rule addressing any one of these areas would provide the Commission sufficient basis to find that the FFD Rule overall results in a substantial increase in protection to public health and safety. Perforce, it follows that when the provisions of the FFD Rule are considered in the aggregate, the rule overall provides a substantial increase in protection.

The Commission also finds that the FFD Rule will result in net cost reductions (*i.e.*, costs of implementing the final FFD Rule are exceeded by cost reductions attributable to the permissive relaxations and clarifications to ambiguous or imprecise regulatory language in the final FFD Rule). The Regulatory Analysis contains a detailed estimate of costs imposed by the FFD Rule, as well as the cost savings attributable to the deletion of ineffective and unnecessary requirements in the current rule. As shown in Table 6 of the Regulatory Analysis, the FFD Rule overall provides significant cost *reductions* (as opposed to imposing additional costs) on nuclear power plant licensees.

In light of the findings above, the Commission finds that the qualitative safety benefits of the FFD Rule, considered in the aggregate, constitute a substantial increase in protection to public health and safety, and that the costs of the FFD Rule (which in reality are cost reductions) are justified in view of the increase in protection to safety that is provided by the integrated requirements embodied in the final FFD Rule.

Conclusion

The Commission has evaluated the backfitting implications of the FFD Rule using two different methodological approaches, in order to gain a clearer understanding of the backfit implications of adopting the FFD Rule. The Commission finds that the Backfit Rule, by itself, does not mandate the use of either approach and that the Commission may use either or both approaches to evaluate the backfitting implications of a rulemaking.⁸

When each proposed change is individually analyzed in isolation, the Commission finds that all but 36 changes constitute a substantial increase in protection to public health and safety, whose cost is justified in light of that substantial increase in protection. With respect to the remaining 36 changes, the Commission finds that they constitute “worthwhile changes” to the FFD regulatory regime embodied in Part 26⁹. Therefore, to the extent that the FFD Rule’s

⁸The Commission does not intend to establish a precedent that broad-scope rulemakings must be analyzed for backfit implications using the bifurcated approach used in this rulemaking. The Commission will consider whether the Staff should be required to include in its rulemaking plan for future rulemakings a Staff recommendation whether the backfit analysis for the contemplated rule should be performed on an aggregate basis or whether individual provisions should be analyzed separately.

⁹The Commission wishes to emphasize that a decision to adopt a proposed requirement constituting a “worthwhile improvement” as an exception to the Backfit Rule should not be made routinely, and should be limited to exceptional situations, *e.g.*, where the underlying purpose of the Backfit Rule is inapplicable, or where it is clear that the Backfit Rule’s criteria, which focus on *safety* benefits and imposed costs, are not relevant considerations (*e.g.*, as in the case of a worthwhile change). The Commission believes that the 36 changes, when viewed in the context of the FFD Rule, are appropriate candidates for adoption as exceptions to the Backfit Rule. The FFD Rule differs from recent Commission rulemakings affecting nuclear power plant licensees in several respects. First, the subject matter of fitness for duty, and drug testing in particular, has been a rapidly-changing field since the FFD Rule was first adopted. The Commission recognized the dynamic nature of FFD when it adopted Part 26, and therefore directed the NRC Staff to “revisit the need for changes to the final rule within 18 months following the implementation date of the rule. March 22, 1989 SRM, SECY-89-30, Final Rulemaking - Fitness-for Duty Programs. While the Commission adopted incremental,

changes are individually evaluated under the Backfit Rule, the Commission could adopt the 36 “worthwhile changes” as exceptions to the Backfit Rule. The Commission also finds, based upon its Backfitting analysis of each individual provision, that no single change (or group of small changes) in the final FFD Rule will likely impose a disproportionate cost impact on licensees or result in benefits (or cost reductions) whose benefits are being used to offset the costs of a large number of rule changes that have little or no safety (or other worthwhile) benefit. Finally, the Commission finds that the changes in the FFD Rule, considered together as an integrated regulatory initiative, provide a substantial increase in protection to public health and safety whose costs are justified in view of the increase in protection to safety that is provided by the integrated requirements embodied in the final FFD Rule (in fact the FFD Rule as a whole results in cost reductions).

Therefore, the Commission has concluded that it is appropriate in this rulemaking to use an aggregate backfit analysis, and therefore adopts the final FFD Rule based upon the finding that the final FFD Rule changes, considered together as an integrated regulatory initiative, provide a substantial increase in protection to public health and safety whose costs are justified in view of the increase in protection that is provided by the integrated requirements embodied in the final FFD Rule. The Commission concludes that its obligations under the Backfit Rule have been satisfied in connection with the adoption of the final FFD Rule.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and the Office of Information and Regulatory Affairs at OMB concurred with this determination on October 22, 1997.

List of Subjects in 10 CFR Part 26

Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power reactors, Protection of information, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following revision to 10 CFR Part 26.

1. 10 CFR Part 26 is revised to read as follows:

PART 26--FITNESS FOR DUTY PROGRAMS

GENERAL PROVISIONS

26.1 Purpose.

narrowly-directed changes to the FFD Rule in 1991 (56 FR 41922, August 26, 1991) and 1994 (59 FR 502, January 5, 1994), this final FFD Rule represents the Commission’s first overall evaluation of the implementation of Part 26 and reconsideration of Part 26.

- 26.2 Scope.
- 26.3 Definitions.
- 26.4 Interpretations.
- 26.6 Exemptions.
- 26.7 Communications
- 26.8 Information collection requirements: OMB approval.

GENERAL PERFORMANCE OBJECTIVES

- 26.10 General performance objectives.

PROGRAM ELEMENTS AND PROCEDURES

- 26.20 Written policy and procedures.
- 26.21 Policy communications and awareness training.
- 26.22 Training of supervisors and escorts.
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- 26.24 Chemical and alcohol testing.
- 26.25 Employee assistance programs (EAP).
- 26.27 Management actions and sanctions to be imposed.
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- 26.29 Protection of information.

INSPECTIONS, RECORDS, AND REPORTS

- 26.70 Inspections.
- 26.71 Recordkeeping requirements.
- 26.73 Reporting requirements.

AUDITS

- 26.80 Audits.

ENFORCEMENT

- 26.90 Violations.
- 26.91 Criminal penalties.

APPENDIX A TO PART 26--GUIDELINES FOR DRUG AND ALCOHOL TESTING PROGRAMS

AUTHORITY: Secs. 53, 81, 103, 104, 107, 161, 68 Stat. 930, 935, 936, 937, 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2111, 2112, 2133, 2134, 2137, 2201, 2297f); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

GENERAL PROVISIONS

§ 26.1 Purpose.

This part prescribes requirements and standards for the establishment and maintenance of certain aspects of fitness-for-duty (FFD) programs and procedures by the licensed nuclear power industry, and by licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM).

§ 26.2 Scope.

(a) The regulations in this part apply to licensees authorized to operate a nuclear power reactor, to possess or use formula quantities of SSNM, or to transport formula quantities of SSNM. Each licensee shall implement an FFD program which complies with this part. The provisions of the FFD program must apply to:

- (1) All persons granted unescorted access to nuclear power plant protected areas;
- (2) Licensee, vendor, or contractor personnel required to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures;
- (3) SSNM licensee and transporter personnel who:
 - (i) Are granted unescorted access to Category IA Material;
 - (ii) Create or have access to procedures or records for safeguarding SSNM;
 - (iii) Make measurements of Category IA Material;
 - (iv) Transport or escort Category IA Material; or
 - (v) Guard Category IA Material; and
- (4) FFD program personnel who:
 - (i) Can link test results with the person who was tested prior to determination of an FFD policy violation;
 - (ii) Make medical or management determinations of fitness;
 - (iii) Make removal or return-to-work decisions; or
 - (iv) Are involved in the selection or notification of employees for testing or in the collection or onsite testing of specimens.

(b) The regulations in this part do not apply to NRC employees, to law enforcement personnel, or offsite emergency fire and medical response personnel while responding onsite, or SSNM transporters who are subject to U.S. Department of Transportation drug or alcohol fitness programs that require random testing for drugs and alcohol. The regulations in this part also do not apply to spent fuel storage facility licensees or non-power reactor licensees who possess, use, or transport formula quantities of irradiated SSNM as these materials are exempt from the Category I physical protection requirements as set forth in 10 CFR 73.6.

(c) Certain regulations in this part apply to licensees holding permits to construct a nuclear power plant. Each construction permit holder, with a plant under active construction, shall comply with §§ 26.10, 26.20, 26.23, 26.70, and 26.73 of this part; shall implement a chemical testing program, including random tests; and shall make provisions for employee assistance programs, imposition of sanctions, appeals procedures, the protection of information, and recordkeeping.

(d) The regulations in this part apply to the Corporation required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter only if the Corporation elects to engage in activities involving formula quantities of strategic special nuclear material. When applicable, the requirements apply only to the Corporation and personnel carrying out the activities specified in § 26.2(a), (3), and (4).

(e) [RESERVED]

(f) Persons performing activities under this part who are covered by a program regulated by another Federal agency or State need be covered by only those elements of a licensee's FFD program not included in the Federal agency or state program as long as all such persons are subject to pre-access (or pre-employment), random, and for-cause urine testing for the drugs specified in the U.S. Department of Health and Human Services (HHS) Mandatory Guidelines and breath testing for alcohol at or below NRC mandated cut-off levels; have their urine specimens tested at a laboratory certified by HHS, the College of American Pathologists or other comparable certification program; have awareness training covering the subjects listed in § 26.21(a)(1), (2), (3), and (5); and access to an impartial and objective procedure for appealing any findings of an FFD violation. Provisions for notification of the licensee(s) granting unescorted access of any FFD violation by the testing agency or organization must be in place.

§ 26.3 Definitions.

Abuse of legal drugs means the use of a legal drug (e.g., alcohol, prescription drugs, over-the-counter drugs) in a manner that constitutes a health or safety hazard to the individual or to others, including on-the-job impairment. Legal or employment actions against an individual for use of legal drugs are presumptive of the abuse of legal drugs.

Aliquot means a portion of a specimen used for testing. It is taken as a sample representing the whole specimen.

Behavioral observation means observation by supervisors in the course of their contacts with other personnel to detect degradations in performance, signs of impairment, or changes in behavior that may indicate the need to evaluate an individual's fitness for duty.

Blood Alcohol Concentration (BAC) means a measure for determining the mass of alcohol in a volume of blood.

Category IA Material means strategic special nuclear material (SSNM) directly useable in the manufacture of a nuclear explosive device, except if:

(1) The dimensions are large enough (at least 2 meters in one dimension, greater than 1 meter in each of two dimensions, or greater than 25 cm in each of three dimensions) to preclude hiding the item on an individual;

(2) The total weight of 5 formula kilograms of SSNM plus its matrix (at least 50 kilograms) cannot be carried inconspicuously by one person; or

(3) The quantity of SSNM (less than 0.05 formula kilogram) in each container requires protracted diversions in order to accumulate 5 formula kilograms.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Confirmatory test means a second analytical procedure to identify the presence of a specific drug or drug metabolite which is independent of the screening test and which uses a different technique and chemical principle from that of the screening test in order to ensure reliability and accuracy. (At this time, gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.) For determining blood alcohol concentration levels, a "confirmatory test" means a second test using another breath alcohol analysis device. Additional information may be obtained by gas chromatography analysis of blood.

Confirmed positive test means a laboratory confirmed positive test result that has been verified as a violation of FFD policy by the Medical Review Officer (MRO) after evaluation. A

"confirmed positive test" for alcohol is obtained as a result of a confirmation of blood alcohol concentration (BAC) levels of 0.04 percent or higher or a BAC of 0.02 percent or higher after an individual has been in a work status for two (2) or more hours or a BAC of 0.03 percent or higher after an individual has been in a work status for more than one (1) hour with a second breath analysis without MRO evaluation.

Contractor means any company or individual with which the licensee has contracted for work or service to be performed inside the protected area boundary, either by contract, purchase order, or verbal agreement.

Custody-and-control form means the form used to document the maintenance of the chain of custody for specimens. (Licensees that test urine specimens for only the five drugs specified in Appendix A to Part 26 and at the cut-off levels prescribed in the HHS Mandatory Guidelines can use the Federal Drug Testing Custody and Control Form (OMB Number 0930-0158). However, this form cannot be used by licensees testing for additional drugs, testing at lower cut-off levels, or when testing blood specimens. Those licensees should use a "look alike" form that accomplishes the same specimen security and accountability tracking purposes.)

Cut-off level means the value set for designating a test result as positive.

HHS-certified laboratory means a laboratory that is certified to perform urine drug testing under the Department of Health and Human Services "Mandatory Guidelines for Federal Workplace Drug Testing Programs," June 9, 1994, (59 FR 29908), and all revisions thereto.

History of substance abuse means having violated an FFD policy and been removed from activities covered by this part at any time, or, during the past 5 years, having (i) used, sold, or possessed illegal drugs; (ii) abused legal drugs; (iii) subverted or attempted to subvert a drug or alcohol testing program; (iv) refused to take a drug or alcohol test; (v) been subjected to a plan for substance abuse treatment (except for self-referral); or (vi) had any legal or employment action taken for alcohol or drug use.

Illegal drugs means those drugs included in Schedules I through V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

Laboratory confirmed positive means the result of a confirmatory test that has established the presence of drugs, or drug metabolites, at a sufficient level to be an indication of prohibited drug use.

Licensee's testing facility means a drug testing facility operated by a licensee or one of its vendors or contractors to perform onsite screening testing of urine specimens.

Medical determination of fitness means the process whereby a licensed physician, who may be the Medical Review Officer, qualified to make such determination examines and interviews an individual and reviews any appropriate and relevant medical records, in accordance with standard clinical procedures, to determine whether there are indications that the individual may be in violation of the licensee's FFD policy or is otherwise unable to safely and competently perform duties. The qualifications for making the determination are related to the fitness issues presented by the patient.

Medical Review Officer means a licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Presumptive positive screening test result means the result of a screening test for drugs and drug metabolites that indicates the presence of some drug or drug metabolite and that has

the potential to be confirmed through gas chromatography/mass spectrometry testing by an HHS-certified laboratory as a laboratory confirmed positive test result, or the result of a screening test for alcohol indicating a BAC of 0.02 percent or greater.

Protected area has the same meaning as in § 73.2(g) of this chapter, an area encompassed by physical barriers and to which access is controlled.

Screening test means an immunoassay screen for drugs or drug metabolites that may be used to eliminate "negative" urine specimens from further consideration or the first breathalyzer test for alcohol.

Strategic Special Nuclear Material (SSNM) has the same meaning as § 73.2(a), uranium-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope), uranium-233, or plutonium.

Substance abuse means the use, sale, or possession of illegal drugs or the abuse of legal drugs or other substances.

Subversion and Subvert the testing process mean an act intended to avoid being tested or to bring about an inaccurate drug or alcohol test result for oneself or others. Acts of subversion can occur at any stage of the testing program including selection and notification of individuals for testing, specimen collection, specimen analysis, and testing result reporting processes, and can include providing a surrogate urine specimen, diluting a specimen (in vivo or in vitro), and adding an adulterant to a specimen.

Supervisor means any person who has the authority or immediate oversight responsibilities to direct or control activities of any other person or persons within the protected area or has ongoing responsibility for the supervision of an individual with unescorted access status while that individual is not in the protected area.

Transporter means a general licensee pursuant to 10 CFR 70.20a, who is authorized to possess formula quantities of Strategic Special Nuclear Material as defined in 10 CFR 73.2 in the regular course of carriage for another or storage incident thereto, and includes the driver or operator of any conveyance, and the accompanying guards or escorts.

Vendor means any company or individual, not under contract to a licensee, providing services in protected areas.

§ 26.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 26.6 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. Any exemptions submitted under this part must meet the provisions of § 50.12 or §70.14, as applicable.

§ 26.7 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part must be addressed to the NRC Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Copies of all communications must be sent to the appropriate regional office and resident inspector. Communications and reports may be delivered in person at the Commission's offices at 11555 Rockville Pike, One White Flint North, Rockville, Maryland, or at the Commission's Public Document Room located at 2120 L Street, NW (Lower Level), Washington, DC.

§ 26.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). OMB has approved the information collection requirements contained in this part under control number 3150-0146.

(b) The approved information collection requirements contained in this part appear in §§ 26.6, 26.20, 26.21, 26.22, 26.23, 26.24, 26.27, 26.28, 26.29, 26.70, 26.71, 26.73, 26.80, and Appendix A.

GENERAL PERFORMANCE OBJECTIVES

§ 26.10 General performance objectives.

Fitness-for-duty programs must:

(a) Provide reasonable assurance that nuclear power plant personnel, transporter personnel, and personnel of licensees authorized to possess or use formula quantities of SSNM, will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties; and

(b) Provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of this part.

PROGRAM ELEMENTS AND PROCEDURES

§ 26.20 Written policy and procedures.

Each licensee subject to this part shall establish and implement written policies and procedures designed to meet the general performance objectives and specific requirements of this part. Each licensee shall retain a copy of its latest written policy and procedures as a record until the Commission terminates the licenses for which the policy and procedures were developed. If any portion of the policies and procedures are superseded, the superseded material must be retained for at least 3 years. As a minimum, written policies and procedures must address fitness for duty through the following:

(a) An overall description of licensee policy on fitness for duty. The policy must address use of and offsite involvement with illegal drugs, abuse of legal drugs, subversion of the testing process, and refusals to provide a specimen for testing. A clear and concise written statement of this policy must be prepared and be in sufficient detail to provide affected individuals with

information on what is expected of them, and what consequences may result from lack of adherence to the policy. This statement must be readily available to all persons subject to the policy.

- (1) As a minimum, the written policy must prohibit the consumption of alcohol--
 - (i) Within an abstinence period of at least 5 hours preceding any scheduled working tour, and
 - (ii) During the period of any working tour.
- (2) Licensee policy should also address other factors that could affect fitness for duty such as mental stress, fatigue, illness, and the use of prescription and over-the-counter medications that could cause impairment.
- (b) A description of programs which are available to personnel desiring assistance in dealing with drug, alcohol, or other problems that could adversely affect the performance of activities within the scope of this part.
- (c) Procedures to be used in testing for drugs and alcohol, including procedures for protecting individuals providing a specimen and the integrity of the specimen, and the quality controls used to ensure the test results are valid and attributable to the correct individual.
- (d) A description of immediate and follow-on actions which will be taken, and the procedures to be used, in those cases where persons who are employed by licensees, vendors, or contractors, and are assigned to duties within the scope of this part, are determined to have--
 - (1) Been involved in the use, sale, or possession of illegal drugs;
 - (2) Consumed alcohol during the mandatory pre-work abstinence period, while on duty, or to excess before reporting to duty as demonstrated with a test that can be used to determine blood alcohol concentration;
 - (3) Attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means; or
 - (4) Refused to provide a specimen for analysis.
- (e) A procedure that will ensure that persons called in to perform an unscheduled working tour are fit to perform the task assigned. As a minimum, this procedure must--
 - (1) Require a statement to be made by a called-in person as to whether he or she considers himself or herself fit to perform the task assigned and whether he or she has consumed alcohol within the length of time stated in the pre-duty abstinence policy;
 - (2) If alcohol has been consumed within this period and the person is called in, require a determination of fitness for duty by breath analysis or other means (collection of urine under § 26.24(a)(3) is not required); and
 - (3) Require the establishment of controls and conditions under which a person who has been called-in can perform work, if necessary, although alcohol has been consumed. Consumption of alcohol during the abstinence period shall not by itself preclude a licensee from using individuals needed to respond to an emergency.
- (f) Licensees seeking to grant unescorted access pursuant to 10 CFR 73.56 to personnel covered by another licensee's FFD program that complies with this part may credit that licensee's program through verification that the individual is currently and will continue to be subject to the random testing and behavioral observation programs of either his or her employer or those of the host licensee.

§ 26.21 Policy communications and awareness training.

- (a) Persons assigned to activities within the scope of this part must be provided with appropriate training to ensure that they understand--

- (1) Licensee policy and procedures, including the methods that will be used to implement the policy;
- (2) The personal and public health and safety hazards associated with the use of illegal drugs and the abuse of legal drugs including alcohol;
- (3) The effect of prescription and over-the-counter drugs and dietary conditions on job performance and on chemical test results, and the role of the MRO;
- (4) Employee assistance programs provided by the licensee; and
- (5) What is expected of them and what consequences may result from lack of adherence to the policy,

(b) Initial training in the five topics in paragraph (a) of this section must be completed before assignment to activities within the scope of this part. Refresher training in those five topics must be completed on a nominal 24-month frequency or more frequently where the need is indicated. A record of the training must be retained for a period of at least 3 years. Licensees may accept training of individuals who have been subject to another Part 26 program and who have had initial or refresher training within the 24 months before assignment provided that training by the accepting licensee in the site-specific topics covered by paragraphs (a) (1), (4), and (5) of this section is completed before the assignment to duties within the scope of this part.

§ 26.22 Training of supervisors and escorts.

(a) Managers and supervisors of activities within the scope of this part must be provided appropriate training to ensure that they understand--

- (1) Their role and responsibilities in implementing the program;
- (2) The roles and responsibilities of others, such as the personnel, medical, and employee assistance program staffs;
- (3) Techniques for recognizing drugs and indications of the use, sale, or possession of drugs;
- (4) Behavioral observation techniques for detecting degradation in performance, impairment, or changes in an individual's behavior; and
- (5) Procedures for initiating appropriate corrective action, to include referral to the employee assistance program.

(b) Persons assigned to escort duties shall be provided appropriate training in techniques for recognizing drugs and indications of the use, sale, or possession of drugs, techniques for recognizing aberrant behavior, and the procedures for reporting problems to supervisory or security personnel.

(c) Initial training for escorts and supervisors employed by licensees must be completed before assignment of duties within the scope of this part, except that for an employee's first assignment to supervisory duties within the scope of this part, the initial training must be completed as soon as feasible but no later than 3 months following this assignment. Initial training for supervisors employed by contractors must be completed before their assignment to duties within the scope of this part or within 10 days after the first assignment to on-site supervisory duties within the scope of this part. Refresher training must be completed on a nominal 12-month frequency, or more frequently where the need is indicated. A written examination on the training material given on a nominal 12-month frequency may be used in lieu of refresher training for escorts and supervisors employed by licensees. The written examination must require a demonstration of adequate knowledge of the areas covered in paragraph (a) of this section. Refresher training for escorts and supervisors employed by

licensees must be completed on a nominal 36-month frequency even if examinations are used to fulfill this requirement during the interim period. A record of the training or examination in lieu of training must be retained for a period of at least 3 years. Licensees may accept training of individuals who have been subject to a Part 26 program and who have had initial or refresher training within the 12 months before assignment, provided that training by the accepting licensee in the topics covered by paragraphs (a) (1), (2), and (5) of this section is completed before assignment to duties within the scope of this part.

§ 26.23 Contractors and vendors.

(a) All contractor and vendor personnel performing activities within the scope of this part for a licensee must be subject to either the licensee's program relating to fitness for duty, or to a program, formally reviewed and approved by the licensee, which meets the requirements of this part. Written agreements between licensees and contractors or vendors for activities within the scope of this part must be retained for the life of the contract and will clearly show that--

(1) The contractor or vendor is responsible to the licensee for adhering to the licensee's fitness-for-duty policy, or maintaining and adhering to an effective fitness-for-duty program, which meets the standards of this part; and

(2) Personnel with a known history of substance abuse or having been denied access or removed from activities within the scope of this part at any nuclear power plant for violations of an FFD policy will not be assigned to work within the scope of this part without the knowledge and consent of the licensee.

(b) Each licensee subject to this part shall assure that contractors whose own fitness-for-duty programs are relied on by the licensee adhere to an effective program, which meets the requirements of this part, and shall conduct audits pursuant to § 26.80 for this purpose.

§ 26.24 Chemical and alcohol testing.

(a) To provide a means to deter and detect substance abuse, the licensee shall implement the following chemical testing programs for persons subject to this part:

(1) (i) Pre-access testing for drugs and alcohol must be conducted within 60 days before the granting of unescorted access to protected areas or assignment to activities within the scope of this part unless the individual:

(A) Has been covered by a program meeting the requirements of this part for at least 30 days during the 60 days immediately previous to the granting of unescorted access, and

(B) Has no history of substance abuse.

(ii) Any negative drug and alcohol test meeting the standards of this part and performed within 60 days before granting unescorted access may serve as the pre-access test. A negative test result must be obtained before the granting of unescorted access unless the individual has no history of substance abuse and has either had a negative test result on a test meeting the standards of this part performed within 6 months before granting unescorted access or has been covered by a program meeting the standards of this part for 2 consecutive weeks during that period.

(2) Random drug and alcohol testing must be unannounced and imposed in a statistically random and unpredictable manner so that all persons in the population subject to testing have an approximately equal probability of being selected and tested. Random testing must include testing during all types of work periods, including weekends, backshifts, and

holidays. The tests must be administered so that a person completing a test is immediately eligible for another unannounced test. At a minimum, random tests must be administered on a nominal weekly frequency and at various times during the day. Reasonable efforts must be made to test persons selected for random testing. Persons off site when selected for testing, and not reasonably available for testing in a timely manner, must be tested at the earliest reasonable and practical opportunity and without notification to the individual until immediately prior to his or her reporting for the test. These tests will also fulfill any return-to-duty testing required for these persons, and must be reported to the NRC as random tests. Random testing must be conducted at an annual rate equal to at least 50 percent of the workforce.

(3)(i) For-cause drug and alcohol testing must be conducted:

(A) Following any observed behavior or physical condition that creates a reasonable suspicion of possible substance abuse;

(B) After accidents involving a failure in individual performance resulting in personal injury, in a radiation exposure or release of radioactivity in excess of regulatory limits, or in actual or potential substantial degradations of the level of safety of the plant if there is reasonable suspicion that the individual's performance contributed to the event; and

(C) After receiving credible information that an individual is abusing drugs or alcohol.

(ii) The individual's unescorted access status must be suspended until the individual is pronounced fit for duty based on a management and medical determination of fitness, except for those instances where an individual tests negative in a for-cause test. If the test is based on suspected use of alcohol and the breath analysis is negative, the individual, if determined fit for duty by a management determination of fitness, may be returned to duty pending results of urinalysis for drugs. For-cause drug and alcohol testing must be conducted as soon as practicable after the occurrence of the event. Except under documented unusual circumstances, such testing must be conducted within no more than 2 hours for an alcohol test and 8 hours for specimen collection for a drug test.

(4) Follow-up testing must be conducted on an unannounced and unpredictable basis to verify continued abstention from the use of substances as covered under this part. An individual must be subject to follow-up testing that is tailored to the individual's medical history, but not less frequently than once every 30 days for 4 months after unescorted access is reinstated and at least once every 90 days for the next 2 years and 8 months if:

(i) unescorted access was reinstated for that individual after a suspension under § 26.27(b)(3), or

(ii) unescorted access will be reinstated for that individual after removal under § 26.27(b)(3), (b)(4), or (c)

(5) Return-to-duty testing must be conducted when a person seeks to regain unescorted access to protected areas of the site in question after an absence from the possibility of being tested under that site licensee's program for more than 60 days or when a person seeks to regain unescorted access after having been denied access under the provisions of § 26.27(b). Any negative drug and alcohol test meeting the standards of this part and performed within 60 days before the granting of unescorted access may serve as the return-to-duty test except in the case of those who have been denied access under the provisions of § 26.27(b). A negative test result must be obtained before the granting of unescorted access unless the individual has no history of substance abuse and either has had a negative test result on a test meeting the standards of this part performed within 6 months before the reinstatement of unescorted access or has been covered by a program meeting the standards of this part for 2 consecutive weeks during that period.

(b) Testing for drugs and alcohol, at a minimum, must conform to the "Guidelines for Drug and Alcohol Testing Programs," issued by the NRC and appearing in Appendix A to this part, hereinafter referred to as the NRC Guidelines. Licensees, at their discretion, may implement programs with more stringent standards (e.g., lower cut-off levels, broader panel of drugs). All requirements in this part still apply to persons who fail a more stringent standard, but do not test positive under the NRC Guidelines. Management actions must be the same with the more stringent standards as if the individual had failed the NRC standards.

(c) Licensees shall test specimens collected under each type of test listed in § 26.24(a) for all substances described in § 2.1(a) of the NRC Guidelines (Appendix A to part 26). In addition, licensees may consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other substances with abuse potential are being used in the geographical locale of the facility and the local workforce. When appropriate, other substances so identified may be added to the panel of substances for testing. Appropriate cut-off limits must be established by the licensee for these substances.

(d)(1) All collected urine and blood specimens must be forwarded to a laboratory certified by HHS, except that licensees may conduct screening tests of urine aliquots to determine which specimens are negative and need no further testing, provided the licensee's staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for the testing are implemented. All such testing of specimens must include tests to ensure specimen validity as required by § 2.7(e) of Appendix A to part 26. Quality control procedures for screening tests by a licensee's testing facility must include the processing of blind performance test specimens and the submission to the HHS-certified laboratory of a sampling of specimens initially analyzed as negative. Except for the purposes discussed in § 26.24(d)(2), access to the results of the above screening tests must be limited to the licensee's testing staff, the MRO, the FFD Program Manager, and the employee assistance program staff, when appropriate.

(2) An individual may not be removed or temporarily suspended from unescorted access or be subjected to other administrative action based solely on a presumptive positive screening test result from any drug test, other than for marijuana or cocaine metabolites, unless other evidence, including information obtained under the process set forth in § 2.7(e) of appendix A indicates that the individual is impaired or might otherwise pose a safety hazard. With respect to onsite screening tests for marijuana and cocaine metabolites, licensee management may be informed and licensees may temporarily suspend individuals from unescorted access or from normal duties or take lesser administrative actions against the individual based on a presumptive positive screening test result provided the licensee complies with the following conditions:

(i) For the drug for which action will be taken, at least 85 percent of the specimens which were determined to be presumptively positive as a result of onsite screening tests during the last 12-month data reporting period submitted to the Commission under § 26.71(d) were subsequently reported as positive by the HHS-certified laboratory as the result of a GC/MS confirmatory test.

(ii) There is no loss of compensation or benefits to the tested person during the period of temporary administrative action.

(iii) Immediately upon receipt of a negative report from the HHS-certified laboratory, any matter which could link the individual to a temporary suspension is eliminated from the tested individual's personnel record or other records.

(iv) No disclosure of the temporary removal or suspension of, or other administrative action against, an individual whose test is not subsequently confirmed as a violation of FFD

policy may be made in response to a suitable inquiry conducted under the provisions of § 26.27(a), a background investigation conducted under the provisions of § 73.56, or to any other inquiry or investigation. For the purpose of assuring that no records have been retained, access to the system of files and records must be provided to licensee personnel conducting appeal reviews, inquiries into an allegation, or audits under the provisions of § 26.80, or to an NRC inspector or other Federal officials. The tested individual must be provided a statement that the records specified in paragraph (d)(2)(iii) of this section have not been retained and must be informed in writing that the temporary removal or suspension or other administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for information concerning removals, suspensions, administrative actions or history of substance abuse.

(e) The period of time allowed between the notification of the individual and the actual collection of a specimen must be kept at a minimum consistent with operational constraints. Whenever practicable, the individual should not be allowed the time or opportunity to obtain materials or take any action that would subvert the testing process or the test results.

(f) The MRO shall complete the review of test results reported by the HHS-certified laboratory and notify licensee management as soon as practicable. The MRO shall report all determinations of violations of the licensee's FFD policy to management in writing and in a manner designed to ensure confidentiality of the information. To assure that action is taken immediately, provisions must be made to ensure that the MRO is able to contact appropriate licensee management at any time. Should the MRO's review not be completed within 14 days of the collection of a specimen, licensee management must be advised of available test results, the status of the review, the reasons for the delay, and appropriate recommendations.

(g) All testing of urine specimens for drugs, except screening tests performed by licensees under paragraph (d) of this section, must be performed in a laboratory certified by HHS for that purpose consistent with its standards and procedures for certification. Except for suspect specimens submitted for special processing (§ 2.7(d) or (e) of Appendix A to part 26), all specimens sent to HHS-certified laboratories must be subject to screening analysis by the laboratory and all specimens screened as presumptively positive must be subject to confirmatory testing by gas chromatography/mass spectroscopy analysis by the laboratory. Licensees shall submit blind performance test specimens to HHS-certified laboratories in accordance with the NRC Guidelines (Appendix A to part 26). Licensees shall ensure that all collected specimens are tested and that laboratories report results for all specimens sent for testing, including blind performance test specimens.

(h) Tests for alcohol must be administered by breath analysis using breath alcohol analysis devices meeting evidential standards described in § 2.7(p)(3) of Appendix A to part 26. If the screening test shows a blood alcohol concentration (BAC) of 0.02 percent or greater, a confirmatory test for alcohol must be performed using another breath alcohol analysis device. A confirmatory test for alcohol indicating a BAC of 0.04 percent or greater must be declared a positive test. A confirmatory test result showing a BAC of 0.02 percent or greater after the individual has been in a work status (including any breaks for rest, lunch, dental/mental appointments, etc.) for two (2) or more hours or a BAC of 0.03 percent or greater after an individual has been in a work status for more than one (1) hour must also be declared a positive test. Further testing for alcohol must be through analysis of blood specimens, and must only be administered if requested by the individual for the purposes of obtaining additional information that could be considered during an appeal pursuant to § 26.28. Such a test must be a gas chromatography analysis of whole blood performed on a blood specimen drawn as soon as possible after the confirmatory breath analysis. Any alcohol in the blood specimen may be

considered together with the elapsed time between the confirmatory test and the collection of the blood specimen.

(i) If an individual has a medical condition that makes collection of breath, blood, or urine specimens difficult or hazardous, the MRO, in consultation with the treating or personal physician, may authorize an alternative evaluation process, tailored to the individual case, for determining whether a violation of FFD policy has occurred, provided this process includes measures to prevent subversion and can achieve results comparable to those produced by urinalysis for illegal drugs and breath analysis for alcohol.

§ 26.25 Employee assistance programs (EAP).

Each licensee subject to this part shall maintain an EAP program to strengthen FFD programs by offering assessment, short-term counseling, referral services, and treatment monitoring to employees with problems that could adversely affect the performance of activities within the scope of this part. Employee assistance programs must be designed to achieve early intervention. The EAP must also provide for confidential assistance except that the EAP staff shall inform licensee management when a determination has been made that any individual's condition constitutes a hazard to himself or herself or others (including those who have self-referred).

§ 26.27 Management actions and sanctions to be imposed.

(a)(1) (i) Before assigning an individual to activities within the scope of this part, as described in § 26.2(a), the licensee shall obtain a written statement from the individual as to whether he or she:

(A) Has in the past 5 years used, sold, or possessed any illegal drugs, or had a legal or employment action taken against him or her for alcohol or drug use;

(B) Has in the past 5 years been determined to have violated an FFD policy, or as a result of action taken in accordance with an FFD policy been denied initial assignment to activities within the scope of this part as described in § 26.2(a), or has been subject to a plan for treating substance abuse (except for self-referral for treatment); or

(C) Has at any time as a result of action taken in accordance with an FFD policy been removed from activities within the scope of this part as described in § 26.2(a).

(ii) Power reactor licensees need not obtain statements responding to the activities listed in § 26.2(a)(3) unless the background investigation conducted in accordance with 10 CFR 73.56 indicates the person was previously employed by a licensee authorized to possess or transport Category I nuclear material.

(2) The statement made under paragraph (a)(1) of this section must include the individual's declaration as to the specific type, duration, and resolution of any such matter.

(3) The licensee shall complete a suitable inquiry on a best-efforts basis to verify the accuracy of the individual's written statement made under paragraphs (a) (1) and (a) (2) of this section. This suitable inquiry should cover at least the past 5 years but in no case less than the past 3 years.

(4) If a record of the type described in paragraphs (a) (1), (2), and (3) of this section is established which raises a concern about the person's history of alcohol or drug use, the new assignment to activities within the scope of this part or granting of unescorted access must be

based upon a management and medical determination of fitness for duty and the establishment of an appropriate follow-up testing program, as specified in § 26.24(a)(4). The restrictions of paragraph (b) of this section must be observed; these restrictions include return-to-duty testing, determination of fitness, and proof of abstinence. To meet the suitable inquiry requirement, the identity of persons denied unescorted access or removed under the provisions of this part and the circumstances for the denial or removal, including test results, will be made available in response to a licensee's, contractor's, or vendor's inquiry supported by a release signed by the individual being investigated that authorizes the disclosure of the information.

(5) Failure by an individual to list reasons for removal or revocation of unescorted access or failure to authorize the release of information is sufficient cause for denial of unescorted access.

(6) Where temporary unescorted access pursuant to 10 CFR 73.56 is to be granted to an individual, the requirements in this paragraph must also be satisfied before such access is provided:

(i) If the individual has not previously been removed for violating a licensee's FFD policy, the licensee must either comply with the requirements of this section for full unescorted access or complete a suitable inquiry to verify the accuracy of the individual's written statement obtained under paragraphs (a) (1) and (a) (2) of this section covering the past year's activities (or document its best efforts in this regard), initiate a suitable inquiry for the balance of the past 5 years, and administer a drug and alcohol test in accordance with the requirements of § 26.24(a)(1). In making the suitable inquiry covering the past year's activities, the licensee may use information received over the telephone if a record of the contents of the telephone call is made and retained, or information received by electronic means such as facsimile or e-mail is retained.

(ii) If the individual has been previously removed for violating a licensee's FFD policy, the temporary access provisions of 10 CFR 73.56 are not applicable and cannot be utilized.

(7) If an individual is returning to a licensee after an absence from the possibility of being tested under that site licensee's program for more than 60 days, the licensee must complete a suitable inquiry not later than 72 hours after unescorted access has been restored to ascertain if there were any substance abuse or other violation of an FFD policy during the absence, and must assure that the requirements for testing in accordance with § 26.24(a)(5) have been satisfied. In making the suitable inquiry, the licensee may use information received over the telephone if a record of the contents of the telephone call is made and retained, or information received by electronic means such as facsimile or e-mail is retained.

(b) Each licensee subject to this part shall, at a minimum, take the following actions. The requirements of this paragraph do not prohibit the licensee from taking more stringent action.

(1) Personnel, including applicants, who are impaired, those whose fitness may be questionable, and those determined to have violated the licensee's FFD policy shall be immediately denied unescorted access or otherwise removed from activities within the scope of this part. These persons may be assigned to or returned to their duties only after impairing or questionable conditions are resolved and the individual is determined to be fit to safely and competently perform activities within the scope of this part by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24(a)(5) must be conducted before the individual may be returned to duty and, when applicable, follow-up testing under § 26.24(a)(4) must be conducted to verify continued abstinence from the use of substances.

(2) Lacking any other evidence to indicate the use, sale, or possession of illegal drugs or use of alcohol on site, the following must be presumed to be an indication of offsite drug or alcohol use in violation of the company FFD policy:

(i) A laboratory confirmed positive test result that is verified by the MRO as a policy violation; or

(ii) A confirmatory breath test for alcohol that indicates the individual had a BAC that violated the standards established in § 26.24(h) during any scheduled working tour.

(3) The first violation of the FFD policy involving a confirmed positive drug or alcohol determination must, at a minimum, result in immediate removal from activities within the scope of this part for at least 14 days and referral to the EAP for assessment and counseling during any suspension period. If the individual is retained by the licensee in an employment status pending reinstatement of unescorted access, plans for treatment, follow-up, and future employment, if applicable, must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period. Such individuals must continue to be covered during any suspension period by the applicable FFD program with respect to behavioral observation if in a work status, chemical testing, and sanctions for violations of the licensee's FFD policy. Before an individual is permitted to be returned to duty or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform such activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24(a)(5) must be conducted before the individual may be returned to duty and follow-up testing under § 26.24(a)(4) must be conducted to verify continued abstinence from the use of substances. Any subsequent violation of FFD policy, including during an assessment or treatment period, must immediately result in revocation of authorization to perform activities described in § 26.2(a) for a minimum of 3 years from the date of removal.

(4) Any individual determined to have been involved in the sale, use, or possession of illegal drugs or the use of alcohol while, as applicable, within a protected area of any nuclear power plant, within a facility that is licensed to possess or use SSNM, or within a transporter's facility or vehicle, must immediately have his or her authorization to perform activities within the scope of this part as described in § 26.2(a) revoked for a minimum of 5 years from the date of revocation.

(5) Persons removed for periods of 3 years or more under the provisions of paragraphs (b)(2), (b)(3), (b)(4), and (c) of this section and who would have been removed under the current standards of a hiring licensee, may be granted unescorted access and assigned duties within the scope of this part by a licensee subject to this part only when the hiring licensee receives satisfactory medical assurance that the person has abstained from the use of illegal drugs and the abuse of legal drugs for at least 3 years. Before an individual is permitted to be returned or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform these activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24(a)(5) must be conducted before the individual may be assigned duties and follow-up testing under § 26.24(a)(4) must be conducted to verify continued abstinence from the abuse of substances. Any further violation of FFD policy must immediately result in permanent revocation of authorization to perform activities described in § 26.2(a).

(6) Paragraphs (b)(3), (4), and (5) of this section do not apply to the misuse of valid prescription or over-the-counter drugs. Licensee sanctions for confirmed misuse of valid

prescription and over-the-counter drugs must be sufficient to deter abuse of legally obtainable substances a substitute for abuse of proscribed drugs.

(c) Any act or attempted act to subvert the testing process, including refusal to provide a specimen for testing, must be a violation of the licensee's FFD policy and must result in revocation of authorization to perform activities described in § 26.2(a) for a minimum of 3 years. Any act or attempted act to subvert the testing process, or resignation before removal for violation of company FFD policy concerning drugs and alcohol must be recorded and provided in response to a suitable inquiry. The specific cause for a removal, e.g., that a laboratory confirmed positive test result was obtained and that the individual resigned before an MRO review, must also be provided in response to a suitable inquiry. A record of these actions must be retained consistent with § 26.71(c) following any revocation of authorization to perform activities described in § 26.2(a).

(d) If a licensee has a reasonable belief that an NRC employee or NRC contractor may be under the influence of any substance, or otherwise unfit for duty, the licensee may not deny access but shall escort the individual. In any instance of this occurrence, the appropriate Regional Administrator must be notified immediately by telephone. During other than normal working hours, the NRC Operations Center must be notified.

§ 26.28 Appeals.

Each licensee subject to this part, and each contractor or vendor implementing an FFD program under the provisions of § 26.23, shall establish a procedure for licensee and contractor or vendor employees and applicants for unescorted access to appeal a determination of a violation of FFD policy. The procedure must provide notice to the individual of the grounds for the determination of a violation of FFD policy, and must provide an opportunity to respond and to submit additional relevant information. The procedure must provide for an objective, impartial review of the facts relating to the determination of a violation of FFD policy. The review must be conducted by persons not associated with the administration of the FFD program, as described in § 26.2(a)(4), and may include internal management. If the appeal is successful, the relevant records must be corrected. A licensee review procedure need not be provided to employees of contractors or vendors when the contractor or vendor is administering its own alcohol and drug testing.

§ 26.29 Protection of information.

(a) Each licensee subject to this part, that collects personal information on an individual for the purpose of complying with this part, shall establish and maintain a system of files and procedures for the protection of the personal information. This system must be maintained until the Commission terminates each license for which the system was developed.

(b) Licensees, contractors, and vendors may not disclose the personal information collected and maintained to persons other than assigned Medical Review Officers, other licensees, contractors or vendors, or their authorized representatives legitimately seeking the information as required by this part for unescorted access decisions and who have obtained a release from current or prospective employees or contractor personnel, NRC representatives, appropriate law enforcement officials under court order, the subject individual or his or her representative designated in writing for specified FFD matters by the subject individual, to those licensee representatives who have a need to have access to the information in performing assigned duties, including medical determinations of fitness and audits of licensee, contractor,

and vendor programs, to the presiding officer in a judicial or administrative proceeding initiated by the subject individual, to persons deciding matters on review or appeal, and to other persons pursuant to court order. This section does not authorize the licensee, contractor, or vendor to withhold evidence of criminal conduct from law enforcement officials.

(c) Upon receipt of a written request by the subject individual, the licensee, contractor, or vendor possessing such records shall promptly provide copies of all records pertaining to the determination of a violation of the licensee's FFD policy, including test results, MRO reviews, and management determinations of results pertaining to the subject individual. Records relating to the results of any relevant laboratory certification review or revocation of certification proceeding shall be obtained from the relevant laboratory and provided to the subject individual upon request.

INSPECTIONS, RECORDS, AND REPORTS

§ 26.70 Inspections.

(a) Each licensee subject to this part and their contractors and vendors shall permit duly authorized representatives of the Commission to inspect, copy, or take away copies of its records and inspect its premises, activities, and personnel as may be necessary to accomplish the purposes of this part.

(b) Written agreements between licensees and their contractors and vendors must clearly show that the--

(1) Licensee is responsible to the Commission for maintaining an effective fitness-for-duty program in accordance with this part; and

(2) Duly authorized representatives of the Commission may inspect, copy, or take away copies of any licensee, contractor, or vendor documents, records, and reports related to implementation of the licensee, contractor, or vendor FFD program under the scope of the contracted activities. This includes documents, records, and reports of FFD service contractors (e.g., contracted HHS-certified laboratory, MRO, EAP, and specimen collection services) related to licensee, contractor, or vendor FFD programs.

§ 26.71 Recordkeeping requirements.

Each licensee subject to this part and each contractor and vendor implementing a licensee approved program under the provisions of § 26.23 shall--

(a) Retain records of inquiries conducted in accordance with § 26.27(a), that result in the granting of unescorted access to protected areas, until 5 years following termination of such access authorizations;

(b) Retain records pertaining to the determination of a violation of the FFD policy and the related personnel actions for a period of at least 5 years or until completion of all legal proceedings related to the violation, whichever is later;

(c) Retain records pertaining to the determination of a violation of the FFD policy of persons whose authorization to perform activities within the scope of this part has been revoked under § 26.27(b)(3), (4), (5) or (c), until the Commission terminates each license under which the records were created; and

(d) Collect and compile FFD program performance data on a standard form and submit the data to the Commission either for a calendar year period (January 1 through December 31)

or a 6-month period (January through June, and July through December) by no later than 60 days after the end of the reporting period. The data for each site (corporate and other support staff locations may be separately consolidated) must include: random testing rate; drugs tested for and cut-off levels, including results of tests using lower cut-off levels and tests for other drugs; workforce populations tested; numbers of tests and results by population, and type of test (i.e., pre-access, random, for-cause, etc.); substances identified; summary of management actions; number of subversion attempts by type; and a list of events reported. The data must be analyzed and appropriate actions taken to correct program weaknesses. The data and analysis must be retained for 3 years. Any licensee choosing to temporarily suspend individuals under the provisions of § 26.24(d) shall report test results by process stage (i.e., onsite screening, laboratory screening, confirmatory tests, and MRO determinations) and the number of temporary suspensions or other administrative actions taken against individuals based on onsite presumptive positive screening test results for marijuana (THC) and for cocaine.

§ 26.73 Reporting requirements.

(a) Each licensee subject to this part shall inform the Commission of significant FFD events including, but not limited to:

(1) Sale, distribution, use, possession, or presence of illegal drugs or use or presence of alcohol within the protected area;

(2) Any acts by any person licensed under 10 CFR part 55 to operate a power reactor, by any supervisory personnel assigned to perform duties within the scope of this part, or by any FFD program personnel as specified in § 26.2(a)(4)--

(i) Involving the sale, use, or possession of a controlled substance;

(ii) Resulting in determinations that such an individual has violated the licensee's FFD policy including subversion as defined in § 26.3;

(iii) Involving use of alcohol within the protected area; or

(iv) Resulting in a determination of unfitness for scheduled work due to the consumption of alcohol.

(3) Any act that would cast doubt on the integrity of the FFD program, including, but not limited to, acts that cast doubt on the honesty and integrity of the FFD program personnel specified in § 26.2(a)(4),

(4) Arrest of a worker for sale, distribution, use, or possession of illegal drugs on or off site.

(b) Notification must be made to the NRC Operations Center by telephone within 24 hours of the discovery of the event by the licensee.

(c) Fitness-for-duty events must be reported under this section rather than reported under the provisions of § 73.71.

(d) By November 30, 1993, each licensee that is authorized to possess, use, or transport formula quantities of SSNM shall certify to the NRC that it has implemented a fitness-for-duty program that meets the requirements of 10 CFR part 26. The certification must describe any licensee cut-off levels more stringent than those imposed by this part.

AUDITS

§ 26.80 Audits.

(a) Each licensee subject to this part shall completely audit the FFD program as needed but no less frequently than every 36 months. Licensees are responsible for determining the appropriate frequency, scope, and depth of additional auditing activities within the 3-year period based on review of program performance indicators such as the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, previous audit findings, and "lessons learned." As soon as reasonably practicable, but not later than 12 months after a significant change in FFD personnel, procedures, or equipment, licensees shall audit the particular program element(s) affected by that change to assure continued program effectiveness. Program elements that must continue to be audited nominally every 12 months include FFD program elements implemented by contractors and vendors under the provisions of § 26.23, testing performed at HHS-certified laboratories, and FFD services provided to the licensee by personnel who are off site or not under the direct daily supervision or observation of licensee personnel. Licensees may accept audits of contractors and vendors conducted by other licensees and need not re-audit the same contractor or vendor for the same period of time. Each sharing utility shall maintain a copy of the audit report, to include findings, recommendations and corrective actions. Licensees retain responsibility for the effectiveness of contractor and vendor programs and the implementation of appropriate corrective action.

(b) Audits must focus on the effectiveness of the program and be conducted by individuals qualified in the subject(s) being audited, and independent of both FFD program management and personnel directly responsible for implementation of the FFD program.

(c) The result of the audit, along with recommendations, if any, must be documented and reported to senior corporate and site management. The audit report must identify conditions adverse to the proper performance of the FFD program, the cause of the condition(s) and, when appropriate, recommend corrective actions. Management shall review the audit findings and take follow-up action, including re-audit of the deficient areas where indicated, to preclude, within reason, repetition of the condition. The resolution of the audit findings and corrective actions must be documented. These documents must be retained for 3 years.

ENFORCEMENT

§ 26.90 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of--

- (1) The Atomic Energy Act of 1954, as amended;
- (2) Title II of the Energy Reorganization Act of 1974; or
- (3) Any regulation or order issued under these Acts.

(b) A court order may be obtained for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act of 1954, for violations of--

- (1) Section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act;
- (2) Section 206 of the Energy Reorganization Act of 1974;
- (3) Any rule, regulation, or order issued under these Sections;
- (4) Any term, condition, or limitation of any license issued under these Sections; or
- (5) Any provisions for which a license may be revoked under section 186 of the Atomic Energy Act of 1954.

§ 26.91 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 26 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 26 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 26.1, 26.2, 26.3, 26.4, 26.6, 26.7, 26.8, 26.90, and 26.91.

APPENDIX A TO PART 26--GUIDELINES FOR DRUG AND ALCOHOL TESTING PROGRAMS

Subpart A--General

- 1.1 Applicability.
- 1.2 Definitions.
- 1.3 Future Revisions.

Subpart B--Scientific and Technical Requirements

- 2.1 The Substances.
- 2.2 General Administration of Testing.
- 2.3 Preventing Subversion of Testing.
- 2.4 Specimen Collection Procedures.
- 2.5 HHS-Certified Laboratory Personnel.
- 2.6 Licensee Testing Facility Personnel.
- 2.7 Laboratory and Testing Facility Analysis Procedures.
- 2.8 Quality Assurance and Quality Control.
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Subpart C--Employee Protection

- 3.1 Protection of Employee Records.

Subpart D--Certification of Laboratories Engaged in Chemical Testing

- 4.1 Use of HHS-Certified Laboratories

Subpart A--General

- 1.1 Applicability.

(a) These guidelines apply to licensees authorized to operate nuclear power reactors and licensees that are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM).

(b) Licensees may set more stringent cut-off levels than specified herein or test for substances other than specified herein and shall inform the Commission of the deviation within 60 days of implementing such change. Licensees may not deviate from the other provisions of these guidelines without the written approval of the Commission.

(c) Only laboratories which are HHS-certified are authorized to perform urine drug testing for NRC licensees, vendors, and licensee contractors.

- 1.2 Definitions.

In addition to the definitions contained in § 26.3, the following definitions apply:

Chain of custody. Procedures to account for the integrity of each specimen by tracking its handling and storage from the point of specimen collection to final disposition of the specimen.

Collection site. A place designated by the licensee where individuals present themselves for the purpose of providing a specimen of their urine, breath, and/or blood to be analyzed for the presence of drugs or alcohol.

Collection site person. A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the specimen(s) provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein. In any case where: a collection is observed or collection is monitored by non-medical personnel, the collection site person must be a person of the same gender as the donor.

Limit of detection (LOD). The lowest concentration of an analyte that an analytical procedure can reliably detect, which should be significantly lower than the established cut-off levels.

1.3 Future Revisions

In order to adapt the rule to changes in the evolving disciplines related to substance abuse and employee fitness and ensure the full reliability and accuracy of drug assays, the accurate reporting of test results, and the integrity and efficiency of drug testing programs conducted under the provisions of 10 CFR Part 26, the Commission may make changes to these Guidelines to reflect improvements in the available science and technology, in response to additional experience, or as other considerations warrant.

Subpart B--Scientific and Technical Requirements

2.1 The Substances.

(a) Licensees shall, at a minimum, test for marijuana, cocaine, opiates, amphetamines, phencyclidine, and alcohol for pre-access, for-cause, random, follow-up, and return-to-duty tests.

(b) Licensees may test for any illegal drugs or any other substances suspected of having been abused and may consider any detected drugs or metabolites when determining appropriate action during a for-cause test, a return-to-duty test after removal from access under § 26.27(b) or (c), any test of an individual who is in a follow-up testing program, or analysis of any specimen suspected of being adulterated or diluted (in vivo or in vitro), substituted, or tampered with by any other means.

(c) Licensees shall establish rigorous testing procedures that are consistent with the intent of these guidelines for any other drugs not specified in these guidelines for which testing is authorized under 10 CFR Part 26, so that the appropriateness of the use of these substances can be evaluated by the Medical Review Officer (MRO) to ensure that individuals granted unescorted access are fit for maintaining access to and for performing duties in protected areas.

(d) Specimens collected under NRC regulations requiring compliance with this part may only be designated or approved for testing as described in this part and shall not be used to conduct any other analysis or test without the permission of the tested individual.

(e) This section does not prohibit procedures reasonably incident to analysis of a specimen for controlled substances (e.g., determination of pH or tests for specific gravity, creatinine concentration, or presence of adulterants).

2.2 General Administration of Testing.

The licensee testing facilities and HHS-certified laboratories described in this part shall develop and maintain clear and well-documented procedures for collection, shipment, and accession of urine and blood specimens under this part. These procedures must include, as a minimum, the following:

(a) Use of a custody-and-control form. The original must accompany the specimen to the HHS-certified laboratory. A copy must accompany any split specimen. The form must be a record on which is retained identity data (or codes) on the individual providing the specimen and information on the specimen collection process and transfers of custody of the specimen. Custody-and-control forms related to determinations of violations of the fitness-for-duty (FFD) policy must be retained as required by § 26.71(b) and (c), or until the completion of all legal proceedings related to the violation, whichever is later. Custody-and-control forms recording specimens with negative test results and no FFD violations or anomalies may be destroyed after appropriate summary information has been recorded for program administration purposes.

(b) Use of a tamper-evident sealing system designed in a manner such that the specimen container top can be sealed against undetected opening, the container can be identified with a unique identifying number identical to that appearing on the custody-and-control form, and space has been provided to initial the container affirming its identity. For purposes of clarity, this requirement assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which one or more specimens and associated paperwork may be transferred and which can be sealed and initialed to prevent undetected tampering.

(d) Written procedures, instructions, and training must be provided as follows:

(1) Licensee collection site procedures and training of collection site personnel shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the individual tested, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A non-medical collection site person shall receive training in compliance with this appendix and shall demonstrate proficiency in the application of this appendix before serving as a collection site person. A medical professional, technologist, or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided the instructions described in § 2.2(d)(3) of this appendix and performs collections in accordance with those instructions.

(3) Collection site persons shall be provided with detailed, clearly-illustrated, written instructions on the collection of specimens in compliance with this part. Individuals subject to testing shall also be provided standard written instructions setting forth their responsibilities.

(4) The option to provide a blood specimen for the purposes of obtaining additional information that could be considered during an appeal pursuant to § 26.28 following a positive confirmatory breath test must be specified in the written instructions provided to individuals tested.

2.3 Preventing Subversion of Testing.

Licensees shall carefully select and monitor persons responsible for administering the testing program (e.g., collection site persons, onsite testing facility technicians, MROs, and those selecting and notifying personnel to be tested), based upon the highest standards for honesty and integrity, and shall implement measures to ensure that these standards are maintained. At a minimum, these measures must ensure that the integrity of such persons is not compromised or subject to efforts to compromise due to personal relationships with any individuals subject to testing.

At a minimum:

(a) Supervisors, co-workers, and relatives of the individual being tested shall not perform any collection, assessment, or evaluation procedures.

(b) FFD program personnel shall be tested by personnel independent of the administration of the FFD program to the extent practicable.

(c) Appropriate background checks and psychological evaluations of the FFD program personnel specified in § 26.2(a) must be completed before assignment of tasks directly associated with the licensee's administration of the program, and must be conducted at least once every 5 years.

(d) Persons, specified in § 26.2(a), responsible for administering the testing program shall be subjected to a behavioral observation program designed to assure that they continue to meet the highest standards for honesty and integrity.

2.4 Specimen Collection Procedures.

(a) Designation of Collection Site. Each drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine or blood specimens to a drug testing laboratory. A properly equipped mobile facility that meets the requirements of this part is an acceptable collection site.

(b) Collection Site Person. A collection site person shall have successfully completed training to carry out this function. In any case where the collection of urine is observed, the collection site person must be a person of the same gender as the donor. Persons drawing blood shall be qualified to perform that task.

(c) Security. Measures shall be provided to prevent unauthorized access which could compromise the integrity of the collection process or the specimen. Security procedures shall provide for the designated collection site to be secure. If a collection site facility cannot be dedicated solely to drug and alcohol testing, the portion of the facility used for testing shall be secured during that testing.

(1) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present, and that undetected access (e.g., through a rear door not in the view of the collection site person) is impossible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the individual or distraction of the collection site person.

(2) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed container is transferred for shipment, the

following minimum procedures shall apply: The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in a mailer or secured for shipment. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under the personal control of the collection site person. These minimum procedures shall apply to the mailing of specimens to licensee testing facilities from collection sites (except where co-located) as well as to the mailing of specimens to HHS-certified laboratories. As an option, licensees may ship several specimens via courier in a locked or sealed shipping container.

(d) Chain-of-Custody. Licensee custody-and-control forms must be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine and blood specimens from one authorized individual or place to another must always be accomplished through chain-of-custody procedures. Since chain-of-custody documentation for each urine specimen must be attached to the specimen bottle and the specimen bottles must be placed in a sealed, tamper-evident shipping container for shipment to the drug testing laboratory, both as required by § 2.4(i), couriers, express carriers, and postal service personnel do not have access to the custody-and-control forms. Therefore, there is no requirement that such personnel document chain of custody on the custody-and-control forms during transit. Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service. Every effort must be made to minimize the number of persons handling the specimens.

(e) Access to Authorized Personnel Only. No unauthorized personnel shall be permitted in any part of the designated collection site where specimens are collected or stored. Only the collection site person may handle specimens before their securement in the mailing or shipping container or monitor or observe specimen collection (under the conditions specified in this part). To promote security of specimens, avoid distraction of the collection site person, and ensure against any confusion in the identification of specimens, a collection site person shall conduct only one collection procedure at any given time. For this purpose, a collection procedure is complete when the specimen container has been sealed and initialed, the custody-and-control form has been executed, and the individual has departed the collection site.

(f) Privacy. Procedures for collecting urine specimens must allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided. For purposes of this appendix, the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute a urine specimen:

(1) The individual has presented, at this or any previous collection, a urine specimen that failed to meet the standards for an acceptable specimen as described in § 2.4(g) (15) of this appendix, or the specimen was determined to be of questionable validity or invalid under the provisions of § 2.7(e) of this appendix unless it was determined by MRO review, after special processing of the specimen as provided in that section, that no violation of the licensee's FFD policy occurred.

(2) The individual has presented a urine specimen that falls outside the normal temperature range; and

(i) the individual declines to provide a measurement of oral body temperature by sterile thermometer, as provided in § 2.4(g)(15) of this appendix; or

(ii) the individual's oral temperature varies by more than 1°C/1.8°F from the temperature of the specimen.

(3) The last urine specimen provided by the individual (i.e., on a previous occasion) was determined to have a specific gravity of less than 1.003 or a creatinine concentration below 20

milligrams per deciliter unless it was determined by MRO review after special processing of the specimen as provided in § 2.7(e) of this appendix that no violation of the licensee's FFD policy occurred.

(4) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the specimen.

(5) The individual has previously been determined to have used a substance inappropriately or without medical authorization and the particular test is being conducted as a part of a rehabilitation program or on return to service after evaluation and/or treatment for a confirmed positive test result.

(g) Integrity and Identity of Specimens. Licensees shall take precautions to ensure that a urine specimen is not adulterated, diluted, or tampered with during the collection procedure, that a surrogate specimen is not provided, that a blood specimen or breath exhalent tube cannot be substituted or tampered with, and that the information on the specimen container and on the custody-and-control form can identify the individual from whom the specimen was collected. The following minimum precautions must be taken to ensure that authentic specimens are obtained and correctly identified:

(1) To deter the dilution of urine specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure, it shall be effectively secured or monitored to ensure it is not used (undetected) as a source for diluting the specimen.

(2) When an individual arrives at the collection site for a urine or breath test, the collection site person shall ensure that the individual is positively identified as the person selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive for a urine or breath test at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) After the individual has been positively identified, the collection site person shall ask the individual to sign a consent-to-testing form. The individual shall not be required to list prescription medications or over-the-counter preparations that he or she can remember using.

(5) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room in which the urine specimen is collected. The individual may retain his or her wallet.

(6) The individual shall be instructed to wash and dry his or her hands prior to urination.

(7) After washing hands prior to urination, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the urine specimen.

(8) The individual may provide his or her urine specimen in the privacy of a stall or otherwise partitioned areas that allows for individual privacy.

(9) The collection site person shall note any unusual behavior or appearance on the custody-and-control form.

(10) In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement for urine specimen collection (e.g., an accident investigation), a public or onsite rest room may be used according to the following procedures. A collection site person of the same gender as the individual shall accompany the individual into the rest room which shall be made secure during the collection procedure. If practicable, a toilet bluing agent must be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain-of-custody procedures. If a collection site person of the same gender is not available, the licensee shall select a same gender person to accompany the individual. This person shall be briefed on relevant collection procedures.

(11) Upon receiving a urine specimen from the individual, the collection site person shall determine whether it contains a quantity of urine sufficient to meet specific licensee testing program requirements. This quantity must be predetermined by each licensee and must take into account all analyses and reanalyses provided for in the licensee's FFD policy. The predetermined quantity for any particular specimen must include at least 30 milliliters for the testing at the HHS-certified laboratory required under § 2.1(a) of this appendix plus an appropriate additional quantity if the licensee tests for additional drugs. Where collected specimens are to be split under the provisions of § 2.7(k) of this appendix, the predetermined quantity must include at least an additional 15 milliliters. The predetermined quantity should also provide for an additional quantity for onsite testing, if the licensee conducts such testing. In cases where the specimen volume is insufficient to fulfill all analysis and reanalysis requirements as predetermined by the licensee, the specimen should be used to the extent possible to meet those requirements in the following order of priority: testing of the specimen at the HHS-certified laboratory, provision for a split specimen, and onsite screening tests. Partial specimens (less than 30 milliliters) should be retained and sent with any subsequently collected specimen(s) for testing at the HHS-certified laboratory. If there is less than the quantity of urine in the container required for HHS-certified laboratory testing, additional urine must be collected. Each successive void must be collected in a separate container. (The temperature of any specimen in its separate container must be measured in accordance with § 2.4 (g)(13) of this appendix, and the specimen must be inspected, sealed, and labeled as described below for a specimen that meets the licensee's full volume requirements.) Each specimen must be sent separately for analysis. The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., normally, an 8 oz. glass of water every 30 minutes, but not to exceed a maximum of 24 oz.). If the individual fails for any reason to provide a quantity of urine sufficient to fulfill all analysis and reanalysis requirements as predetermined by the licensee, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(12) After the urine specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(13) Immediately after the urine specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement must in no case exceed 4 minutes, and may need to be less because of the ambient temperature.

(14) If the temperature of a urine specimen is outside the range of 32.5°-37.7 °C/90.5°-99.8°F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person. Both specimens shall be forwarded to the laboratory for testing. Immediately after a urine specimen is collected, the collection site person shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. Any unusual findings must be noted on the custody-and-control form.

(15) A specimen acceptable for further processing is free of any contaminants, meets the required quantity of at least 30 ml, and is within the acceptable temperature range.

(i) An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(ii) If there is a reason to believe that the individual may have altered or substituted the specimen because one or more of the acceptance criteria is not met or there is other reason to believe that the individual is attempting to subvert the testing process, another specimen must be collected immediately under direct observation of a same gender collection site person. If a collection site person of the same gender is not available, the licensee shall select a same gender observer. The observer shall be briefed on relevant collection procedures. The same measurements must be performed on the second specimen, and both specimens must be forwarded to the laboratory for testing.

(16) All urine specimens suspected of being adulterated or found to be diluted shall be forwarded to the laboratory for testing.

(17) Whenever there is reason to believe that a particular individual may have altered or substituted a specimen or may alter or substitute the urine specimen to be provided, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person. Where appropriate, measures will be taken to prevent additional hydration.

(18) Alcohol breath tests must be performed by using evidential-grade equipment as specified in § 2.7(p)(3) of this appendix. The equipment must be operated in accordance with the manufacturer's instructions by individuals trained and proficient in the use of the equipment. If there is reason to believe a source of alcohol in the mouth exists (e.g., breath freshener or stomach contents) and the testing device does not have built-in protection for the condition, the collection of the first screening breath specimen must be delayed 15 minutes to allow for dissipation of the material. If the analysis of the first screening breath specimen is essentially zero (less than 0.01 percent blood alcohol concentration [BAC]), the test is considered negative and no further testing is required. For each individual whose first screening breath specimen is at or above 0.01 percent BAC, a second screening breath specimen is to be collected and compared on the same equipment as the first screening breath specimen after 2 minutes but no later than 10 minutes after the first specimen is collected. If the two specimens are within plus or minus 10 percent of the average of the two measurements, then the screening test result is considered accurate. If the screening test result is not accurate, the series of two screening breath tests must be repeated on another evidential-grade breath analysis device ensuring that the plus or minus 10 percent accuracy is achieved. If the result of the screening test is greater or equal to 0.02 percent BAC, a confirmatory test must be accomplished. The confirmatory test is a repeat of the screening test procedure done on another evidential-grade breath analysis device.

(19) If the alcohol breath tests indicate that the individual is positive for a BAC at or above the 0.04 percent cut-off level or that the individual may have been positive for a BAC at

or above the 0.04 percent cut-off level during any scheduled working tour (i.e., has a confirmatory test result between 0.02 percent BAC and 0.04 percent BAC), the individual may request a blood test, at his or her discretion, for the purpose of obtaining additional information that could be considered during an appeal. The blood specimen should be drawn immediately, if possible. All vacuum tube and needle assemblies used for blood collection must be factory-sterilized. The collection site person shall ensure that they remain properly sealed until use. Antiseptic swabbing of the skin must be performed with a nonethanol antiseptic. Sterile procedures must be followed when drawing blood and transferring the blood to a storage container; in addition, the container must be sterile and sealed.

(20) Both the individual being tested and the collection site person shall keep urine and blood specimens in view at all times before their being sealed and labeled. If a urine specimen is split (as described in § 2.7(k)) and if any specimen is transferred to a second container, the collection site person shall request the individual to observe the splitting of the urine specimen or the transfer of the specimen and the placement of the tamper-evident seal over the container caps and down the sides of the containers.

(21) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (h) through (j) of this section.

(22) The collection site person shall place securely on each container an identification label which contains the date, the individual's specimen number, and any other identification information provided or required by the drug testing program. If separate from the labels, the tamper-evident seals shall also be applied.

(23) The individual shall initial the identification labels on the specimen bottles for the purpose of certifying that it is the specimen collected from him or her. The specimen bottles must be securely sealed to prevent undetected tampering. The individual must also be asked to read and sign a statement on the custody-and-control form certifying that the specimens identified as having been collected from him or her are, in fact, the specimens that he or she provided.

(24) Agreement of the MRO, other designated medical professional, or a higher level supervisor of the collection site person, must be obtained in advance of each decision to obtain a urine specimen under direct observation as specified in § 2.4(g)(15).

(25) The collection site person shall complete the custody-and-control forms for both the primary specimen and the split specimen, if collected, and shall certify proper completion of the collection.

(26) The specimens and custody-and-control forms are now ready to be packaged for transfer to the laboratory or the licensee's testing facility. If the specimens are not immediately prepared for shipment, they shall be appropriately safeguarded during temporary storage.

(27) While any part of the above chain-of-custody procedures is being performed, it is essential that the specimens and custody documents be under the control of the involved collection site person. The collection site person must not leave the collection site in the interval between presentation of the specimen by the individual and securement of the specimens with identifying labels bearing the individual's specimen identification numbers and seals initialed by the individual. If the involved collection site person leaves his or her work station momentarily, the sealed specimens and custody-and-control forms must be taken with him or her or must be secured. If the collection site person is leaving for an extended period of time, the specimens must be packaged for transfer to the laboratory before he or she leaves the collection site.

(h) Collection Control. To the maximum extent possible, collection site personnel must keep the individual's specimen containers within sight both before and after the individual has

urinated or provided a blood specimen. After the specimen is collected and whenever urine specimens are split, they must be properly sealed and labeled to prevent undetected tampering. The collection site person shall sign or initial and date the specimen seal. A custody-and-control form must be used for maintaining control and accountability of each specimen including split specimens from the point of collection to final disposition of the specimen. The date and purpose must be documented on the custody-and-control form each time a specimen is handled or transferred, and every individual in the chain of custody must be identified. Every effort must be made to minimize the number of persons handling specimens.

(i) Specimen Preparation for Transportation to Laboratory or Testing Facility. Collection site personnel shall arrange to transfer the collected specimens to the drug testing laboratory or licensee testing facility. Licensees shall take appropriate and prudent actions to minimize false negative results from specimen degradation. At a minimum, collected urine specimens must be shipped to the HHS-certified laboratory, or cooled to not more than 6 degrees centigrade (42.8°F), within 6 hours of collection. Specimens must be sent to the HHS-certified laboratory as soon as reasonably possible but, except under unusual circumstances, the time between specimen shipment and receipt of the specimen at the HHS-certified laboratory should not exceed 48 hours, or the time between shipment and the screening test at the HHS-certified laboratory exceed 72 hours. The collection site personnel shall ensure that the custody-and-control form is packaged with its associated urine specimen bottle. Sealed and labeled specimen bottles, with their associated custody-and-control forms, being transferred from the collection site to the drug testing laboratory must be placed in a second, tamper-evident shipping container which must be designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal.

(j) Failure to Cooperate. If the individual attempts to subvert the testing process or otherwise refuses to cooperate with the urine collection or breath analysis process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen; provides incorrect or incomplete personal information), then the collection site person shall inform the appropriate authority and shall document the non-cooperation on the specimen custody-and-control form. The failure to cooperate must be reported immediately to the MRO, the FFD Program Manager, or to other management having a need to know, as appropriate, for further action. The provision of a blood specimen for use in an appeal of a positive breath test for alcohol must be entirely voluntary, and must be at the individual's option.

2.5 HHS-Certified Laboratory Personnel.

(a) Day-to-Day Management of the HHS-certified Laboratories.

(1) The HHS-certified laboratory shall have a responsible person to assume professional, organizational, educational, and administrative responsibility for the laboratory's drug testing facilities.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the appropriate State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology (e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology).

(3) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual must be reviewed, signed, and dated by this responsible person whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect must be maintained. (Specific contents of the procedure manual are described in § 2.7(p) of this appendix.)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that test results are not reported until all corrective actions have been taken and he or she can assure that the test results provided are accurate and reliable.

(b) Test Validation. The laboratory's urine drug testing facility shall have a certifying scientist(s) as defined in section 1.2 of the HHS Guidelines, June 9, 1994; 59 FR 29908 who reviews all pertinent data and quality control results to attest to the validity of the laboratory's test reports. A laboratory may designate certifying scientists who are qualified to certify only results that are negative on the initial test and certifying scientists who are qualified to certify both initial and confirmatory tests.

(c) Day-to-Day Operations and Supervision of Analysts. The laboratory's urine drug testing facility shall have an individual(s) to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the

review, interpretation, and reporting of test results; maintenance of chain-of-custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) Other Personnel. Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) Training. The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) Files. Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

2.6 Licensee Testing Facility Personnel.

(a) Day-to-Day Management of Operations. Any licensee testing facility shall have an individual to be responsible for day-to-day operations and to supervise the testing technicians. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the licensee testing facility, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; and proper remedial actions to be taken in response to detecting aberrant test or quality control results.

(b) Other Personnel. Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(c) Files. Licensees' testing facility personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate; and appropriate data to support determinations of honesty and integrity conducted in accordance with § 2.3 of this appendix.

2.7 Laboratory and Testing Facility Analysis Procedures.

(a) Security and Chain of Custody.

(1) HHS-certified drug testing laboratories and any licensee testing facility shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records and split specimens are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times in the HHS-certified laboratory and in the licensee's testing facility. Documentation of individuals accessing these areas, dates, and times of entry and purpose of entry must be maintained.

(2) Laboratories and testing facilities shall use chain-of-custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate custody-and-control form each time a

specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete custody-and-control forms for those specimens or aliquots as they are received.

(b) Receiving.

(1) When a shipment of specimens is received, laboratory and the licensee's testing facility personnel shall inspect each package for evidence of possible tampering and compare information on specimen containers within each package to the information on the accompanying custody-and-control forms. Any direct evidence of tampering or discrepancies in the information on specimen containers and the licensee's custody-and-control forms attached to the shipment must be reported by the HHS-certified laboratory within 24 hours to the licensee in the case of HHS-certified laboratories and must be noted on the laboratory's custody-and-control form which must accompany the specimens while they are in the laboratory's possession. Indications of tampering with specimens at a testing facility operated by a licensee must be reported within 8 hours to senior licensee management.

(2) Specimen containers will normally be retained within the laboratory's or testing facility's accession area until all analyses have been completed. Aliquots and the custody-and-control forms shall be used by laboratory or testing facility personnel for conducting screening and confirmatory tests, as appropriate.

(c) Short-Term Refrigerated Storage. Specimens that do not receive a screening test and, if appropriate, a confirmatory test within 1 day of arrival at the HHS-certified laboratory, or are not shipped within 6 hours of collection from the licensee's collection or testing facility as well as any retained split specimens must be placed in secure refrigeration units or other means of securely maintaining the specimens in a chilled condition until testing or shipment. Temperatures must not exceed 6°C/43°F. Contingency measures must be available to maintain the specimens in a chilled state in case of prolonged power failure.

(d) Specimen Processing. Urine specimens identified as presumptively positive or as questionable for adulteration or dilution by a licensee's testing facility must be shipped to an HHS-certified laboratory for testing. Laboratory facilities for drug testing will normally process urine specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either screening or confirmatory tests at either the licensee's testing facility or an HHS-certified laboratory, every batch must contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test specimens must appear as ordinary specimens to laboratory analysts. Special processing may be conducted to analyze specimens suspected of being adulterated or diluted (including hydration). Any evidence of adulteration or dilution, and any detected trace amounts of drugs or metabolites, must be reported to the MRO. The MRO shall report any adulteration or dilution evidence (excluding hydration resulting from an acceptable reason) to management immediately.

(e) Determining Specimen Validity.

(1) Licensees should take prudent and appropriate actions to assure specimen validity. Devices used to determine validity of the specimen on site and at HHS-certified laboratories must be accurate and not contaminate the specimen. At a minimum, the following actions must be taken. Equivalent processes may be used when acceptable to the HHS laboratory certification program; additional measures may be taken as changes to subversion technology take place. Specimens that are to be tested at the licensee's testing facility must first be tested for creatinine, specific gravity, pH, and nitrites. If a specimen's creatinine concentration is less

than 20 milligrams per deciliter, if the specific gravity is less than 1.003, if the pH is less than 4.8 or greater than 7.8, if the nitrite concentration is equal to or greater than 500 micrograms per milliliter, or if there is other evidence of adulterants, the specimen must be sent to the HHS-certified laboratory for processing. HHS-certified laboratories must test these specimens and all other urine specimens forwarded under the provisions of § 26.24(d)(1) to determine their validity and to detect evidence of adulteration or dilution. At a minimum, such testing must include analysis for creatinine, pH, and nitrites (and specific gravity when acquisition and certification of automated methods are completed) before being subjected to screening testing. If a specimen's creatinine concentration is less than 20 milligrams per deciliter, the laboratory must measure the specimen's specific gravity.

(2) A valid specimen acceptable for testing using the cut-off levels in §§ 2.7(f)(1) and 2.7(g)(2) of this appendix, at either a licensee's testing facility or an HHS-certified laboratory, is free of adulterants and has a creatinine level equal to or greater than 20 milligrams per deciliter, a pH concentration between 4.8 and 7.8 (inclusive), a nitrite concentration less than 500 micrograms per milliliter, and a specific gravity equal to or greater than 1.003 (when applicable). Specimens not meeting these standards are to be considered either adulterated, diluted, or of questionable validity.

(3) A specimen is invalid if it is either diluted or adulterated. A specimen is invalid if it has a creatinine concentration equal to or less than 7 milligrams per deciliter in combination with a specific gravity measurement equal to or less than 1.001 or in combination with a specific gravity measurement equal to or greater than 1.020, a pH measurement equal to or less than 3.5 or equal to or greater than 11.0, a nitrite concentration equal to or greater than 500 micrograms per milliliter, or if it has detectable adulterants. When a laboratory determines that a specimen is invalid, it need not conduct further testing but must report the possibly diluted or adulterated condition and the quantitated results of all testing to the MRO.

(4) A specimen of questionable validity is a specimen that contains no detectable adulterants but shows evidence of dilution by having a combined creatinine/specific gravity result that falls between a creatinine concentration greater than 7 milligrams per deciliter in combination with a specific gravity greater than 1.001 and a creatinine concentration of less than 20 milligrams per deciliter in combination with a specific gravity of less than 1.003, or by having a pH concentration greater than 3.5 but less than 4.8 or greater than 7.8 but less than 11.0. Specimens determined to be of questionable validity must be subject to screening testing using FDA-approved analytical kits having the lowest concentration levels marketed for the screening technology(ies) being used. The responses of questionable donor specimens must be compared to the acceptable range of negative screening control responses. Those specimens that have responses that are greater than the negative control responses must be subject to confirmation testing by GC/MS at the laboratory's limit of detection (LOD). Such testing need be conducted only for the substance(s) responded to in the screening test. Quantified test results must be reported to the MRO. Negative screening results for this special processing must be reviewed by the MRO, and, if the MRO has reason to believe that the dilution is the result of a subversion attempt, the specimen must also be subject to GC/MS testing at the laboratory's LOD.

(5) When the MRO cannot determine if the specimen is valid or invalid, another specimen must be collected as soon as possible under the direct observation of a same gender collection site person.

(f) On-site and Laboratory Screening Tests.

(1) For the analysis of urine specimens, any screening test performed by a licensee's testing facility and the screening test performed by an HHS-certified laboratory must use an

immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. Pending HHS (SAMSHA) review and approval of non-instrumented immunoassay testing devices, such devices shall not be used to test for drugs of abuse in NRC-regulated FFD programs. Non-instrumented devices may be used for the tests to determine specimen validity required by § 2.7(e). The screening test of breath for alcohol performed at the collection site must use a breath measurement device which meets the requirements of § 2.7(p)(3). The following cut-off levels must be used when screening specimens to determine whether they are negative for the indicated substances:

Screening test cut-off level (ng/ml)

Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites ¹	300
Phencyclidine	25
Amphetamines	1,000
Alcohol ²	0.04% BAC

¹25 ng/ml is immunoassay specific for free morphine.

²Percent, by weight, of alcohol in a person's blood shall be based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath.

In addition, licensees may specify more stringent cut-off levels. In these cases, the results of HHS screening tests must be reported for both levels. Only the more stringent tests need be conducted, and the results for the cut-off levels above may be calculated.

(2) The list of substances to be tested and the cut-off levels, along with the procedures, quality controls, and standards applicable to specimen collection, analysis, and validity, are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant such changes.

(3) Multiple screening tests (also known as rescreening) for the same drug class may be performed only on:

(i) presumptively positive specimens (e.g., a presumptive positive screening test result for amphetamines) only when needed to reduce the effect of possible cross reactivity due to structural analogs;

(ii) those specimens where a valid analytical result cannot be obtained using one particular immunoassay technique due to interference in the assay (e.g., prescription medication); or

(iii) presumptively positive specimens that appear to have a high concentration of drugs or metabolites to determine an appropriate dilution requirement for GC/MS confirmation analysis.

(g) Confirmatory Test.

(1) Specimens which test negative as a result of the HHS-certified laboratory screening test must be reported as negative to the licensee and will not be subject to any further testing unless special processing of the specimen is desired because adulteration or dilution is suspected.

(2) Except as required by § 2.7(e), all specimens identified as presumptively positive on the screening test performed by an HHS-certified laboratory must be confirmed using GC/MS techniques at the cut-off values listed in this paragraph for each drug, or at the cut-off values required by the licensee's unique program, where differences exist. All confirmations must be made by quantitative analysis. Concentrations which exceed the linear region of the standard curve must be documented in the laboratory record as "greater than highest standard curve value."

Confirmatory test cut-off level (ng/ml)	
Marijuana metabolite ¹	15
Cocaine metabolite ²	150
Opiates:	
Morphine	300
Codeine	300
6-Acetylmorphine ³	10
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine ⁴	500
Alcohol ⁵	0.04% BAC

¹Delta-9-tetrahydrocannabinol-9-carboxylic acid.

²Benzoylcegonine.

³Test for 6-AM when the confirmatory test shows a morphine concentration exceeding 2,000 ng/ml.

⁴Specimen must also contain amphetamine at a concentration \geq 200 ng/ml.

⁵Percent, by weight, of alcohol in a person's blood shall be based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath.

In addition, licensees may specify more stringent cut-off levels. In these cases, the results must be reported for both levels. Only the more stringent tests need be conducted, and the results for the cut-off levels above may be calculated.

(3) The analytic procedure for analysis of blood specimens voluntarily provided by individuals testing positive for alcohol on a breath test must be gas chromatography analysis.

(4) The list of substances to be tested and the cut-off levels, along with the procedures, quality controls, and standards applicable to specimen collection, analysis, and validity, are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant such changes.

(5) Specimens that have a positive GC/MS test result for amphetamines must be tested for the *d* and *l* isomers. The results of this additional test must be reported to the MRO. Laboratory quality control and inspection criteria must be included for this additional test.

(h) Reporting Results.

(1) The HHS-certified laboratory shall report test results to the licensee's MRO within 5 working days (6 for suspected amphetamines) after receipt of the specimen by the laboratory. Before any test result is reported, the results of screening tests, confirmatory tests, and quality control data, as applicable, must be reviewed and the test certified as an accurate report by the responsible individual at the laboratory. The report must identify the substances tested for, whether positive or negative; the cut-off(s) for each; the specimen number assigned by the licensee; any indications of tampering, adulteration, or dilution that may be present; and the drug testing laboratory specimen identification number.

(2) The HHS-certified laboratory and any licensee testing facility shall report as negative all specimens, except suspect specimens being analyzed under special processing, which are negative on the screening test or negative on the confirmatory test. Specimens testing positive on the confirmatory analysis must be reported positive for a specific substance. Except as provided in § 26.24(d), presumptive positive results of screening testing at the licensee's testing facility will not be reported to licensee management. The MRO's staff may perform routine administrative support functions, including receipt of test results and scheduling interviews for the MRO.

(3) The MRO may routinely obtain from the HHS-certified laboratory, and the laboratory must provide, quantitation of test results. The MRO may only disclose quantitation of test results for an individual to licensee management if required in an appeals process, or to the individual under the provisions of § 26.29(c). (This does not preclude the provision of program performance data under the provisions of § 26.71(d).) Quantitation of negative tests for urine specimens shall not be disclosed, except where deemed appropriate by the MRO for proper disposition of the results of tests of suspect specimens. Alcohol quantitation for a blood specimen must be provided to licensee management with the MRO's evaluation.

(4) The laboratory may transmit results to the MRO by various electronic means (e.g., teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone from HHS-certified laboratory personnel to the MRO. The HHS-certified laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall retain the original custody-and-control form and must send only to the MRO certified true copies of the original custody-and-control form and the test report. In the case of a laboratory-confirmed positive or special processing of suspect specimens, the document must be signed by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports. Laboratories must retain these documents consistent with the requirements contained in § 2.2(a) of this appendix.

(6) The HHS-certified laboratory and the licensee's testing facility shall provide to the licensee official responsible for coordination of the FFD program a monthly statistical summary of urinalysis and blood testing and shall not include in the summary any personal identifying information. Screening test data from the licensee's testing facility and the HHS-certified laboratory, and confirmation data from HHS-certified laboratories, must be included for test results reported within that month. Normally this summary must be forwarded from HHS-certified laboratories by registered or certified mail and from the licensee's testing facility not more than 14 calendar days after the end of the month covered by the summary. The summary must contain the following information:

- (i) Screening Testing:
 - (A) Number of specimens received;
 - (B) Number of specimens reported out; and

- (C) Number of specimens screened positive for:
 - (1) Marijuana metabolites;
 - (2) Cocaine metabolites;
 - (3) Opiate metabolites;
 - (4) Phencyclidine;
 - (5) Amphetamines; and
 - (6) Alcohol.
- (ii) Confirmatory Testing:
 - (A) Number of specimens received for confirmation;
 - (B) Number of specimens confirmed positive for:
 - (1) Marijuana metabolites;
 - (2) Cocaine metabolites;
 - (3) Morphine, codeine;
 - (4) Phencyclidine;
 - (5) Amphetamines;
 - (6) Methamphetamines; and
 - (7) Alcohol.
 - (7) The statistics shall be presented for both the cut-off levels in these guidelines and any more stringent cut-off levels which licensees may specify. The HHS-certified laboratory and the licensee's testing facility shall make available quantitative results for all samples tested when requested by the NRC or the licensee for which the laboratory is performing drug testing services.
 - (8) Unless otherwise instructed by the licensee in writing, all records pertaining to a given urine or blood specimen shall be retained by the HHS-certified drug testing laboratory and the licensee's testing facility for a minimum of 2 years.
 - (i) Long-Term Storage. Long-term frozen storage (-20° C or less) ensures that any urine specimens that have been associated with personnel actions will be available for any necessary retest during administrative or disciplinary proceedings. Unless otherwise authorized in writing by the licensee, HHS-certified laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens that have been confirmed positive, or that have been adulterated or diluted. Within this 1-year period, a licensee or the NRC may request the laboratory to retain the specimen for an additional period of time. If no such request is received, the laboratory may discard the specimen after the end of 1 year. The laboratory must maintain any specimens under legal challenge for an indefinite period. Any split specimens retained by the licensee must be transferred into long-term storage upon determination by the MRO that the specimen has a laboratory confirmed positive test.
 - (j) Retesting Specimens. Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite. For the retesting of specimens that have been determined to have been adulterated or diluted, the retest need only substantiate the information that the MRO used to make the initial determination.
 - (k) Split Specimens. Urine specimens may be split, at the licensee's discretion, into two parts at the collection site in quantities described in § 2.4(g)(11). One part of each specimen (hereafter called the primary specimen) must be analyzed by the licensee's testing facility or the HHS-certified laboratory for the licensee's purposes as described in this appendix. The other part of the specimen (hereafter called the split specimen) may be withheld from transfer to the laboratory, sealed, and stored in a secure manner by the licensee until all processing of the primary specimen has been completed. If the primary specimen is determined to be negative

and free of any evidence of subversion, the split specimen in storage may be destroyed. If the presumptive positive screening test result of a primary specimen has been confirmed, or if the primary specimen is determined to have been subject to adulteration, dilution, or other means of testing subversion, the tested individual may request in a timely manner (as established by the licensee) that the split specimen be tested. The individual must be informed of this option, and the split specimen can be tested only at the request of the individual. The split specimen must be forwarded as soon as practicable, but in no case more than 3 week days (Monday to Friday, not including holidays) following the day of the request to another HHS-certified laboratory that did not test the primary specimen. The chain-of-custody and testing procedures to which the split specimen is subject must be the same as those used to test the primary specimen and must meet the standards for retesting specimens (i.e., the quantitation of the result is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite or substantiate the previous information ([paragraph 2.7(j)]). The quantitative results of testing of the split specimen shall be made available to the MRO and to the individual tested. Except as noted in this section, all other requirements of this appendix applicable to primary specimens shall also be applicable to split specimens. If the result of the test of the split specimen fails to reconfirm or substantiate the result reported for the primary specimen, the MRO shall take into account the primary specimen test result, the data regarding presence or absence of drug or metabolite in the split specimen, any evidence of subversion, and any other relevant information to determine whether the test results should be verified as an FFD policy violation. The licensee must investigate, take corrective action as appropriate in response to, and report to the NRC failure to reconfirm as directed in § 2.8(f) of Appendix A.

(l) Subcontracting. HHS-certified laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the licensee. The laboratory must be capable of testing the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) and of whole blood and confirmatory GC/MS methods specified in these guidelines.

(m) Laboratory Facilities.

(1) HHS-certified laboratories shall comply with applicable provisions of any State licensure requirements.

(2) HHS-certified laboratories must have the capability, at the same laboratory premises, of performing screening and confirmatory tests for each drug and drug metabolite for which service is offered and for analysis of whole blood for alcohol content (BAC). Any licensee testing facilities must have the capability, at the same premises, of performing specimen validity tests required by § 2.7(e) and screening tests for each drug and drug metabolite for which testing is conducted. Breath tests for alcohol may be performed at the collection site.

(n) Inspections and Audits. The NRC and any licensee using an HHS-certified laboratory reserve the right to inspect or audit the laboratory at any time. Licensee contracts with HHS-certified laboratories for drug testing and analyses of whole blood for alcohol content (BAC), as well as contracts for collection site services, must permit the NRC and the licensee to conduct unannounced inspections and audits and to obtain all information and documentation reasonably relevant to the inspections and audits. Licensee contracts with HHS-certified laboratories must also provide the licensee and the NRC with the ability to obtain copies of any documents, including reviews and inspections pertaining to the laboratory's certification by HHS, and any other data that may be needed to assure that the laboratory is performing its testing and quality control functions properly and that laboratory staff and procedures meet applicable requirements. Annual licensee inspections and audits of HHS-certified laboratories

need not duplicate areas inspected in the most recent HHS certification inspection, but only if the licensee reviews the HHS certification inspection records and reports to ascertain the areas covered by the HHS certification inspection. In addition, before the award of a contract, the licensee shall carry out pre-award inspections and evaluation of the procedural aspects of the laboratory's drug testing operation. If an HHS-certified laboratory loses its certification, in whole or in part, a licensee is permitted to immediately use an HHS-certified laboratory that has been audited by another NRC licensee having the same drug panel and cut-off levels. The licensee shall audit the newly contracted HHS-certified laboratory within 3 months. The NRC reserves the right to inspect a licensee's testing facility at any time.

(o) Documentation. HHS-certified laboratories and the licensee's testing facility shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by the NRC or by any licensee for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain-of-custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The HHS-certified laboratory and the licensee's testing facility shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(p) Additional Requirements for HHS-Certified Laboratories and Licensees' Testing Facilities.

(1) Procedure manual. Each laboratory and licensee's testing facility shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cut-off values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect must be maintained as part of the manual. Each HHS-certified laboratory shall retain a copy of its latest procedure manual as a record until at least 2 years after it is no longer under contract to an NRC licensee to test specimens for drugs. Each licensee that conducts onsite testing shall retain a copy of its latest procedure manual as a record until it is no longer conducting on-site testing of specimens of urine for drugs. Superseded material must be retained for at least 3 years.

(2) Standards and controls. HHS-certified laboratory standards and controls shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date. All standards and controls used to calibrate alcohol breath analysis equipment and equipment used at licensees' testing facilities for conducting screening tests must be current and valid for their purpose.

(3) Instruments and equipment.

(i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) Alcohol breath analysis equipment must be an evidential-grade breath alcohol analysis device of a brand and model that conforms to National Highway Traffic Safety Administration (NHTSA) standards (49 FR 48855; December 14, 1984, or 58 FR 48705;

September 17, 1993, or as subsequently amended) and to any applicable State statutes. Calibration units used to calibrate alcohol breath analysis equipment must be of a brand and type that conform to NHTSA standards (62 FR 43416; August 13, 1997, or as subsequently amended) and to any applicable State statutes and must be suitable for meeting the alcohol testing requirements of part 26.

(iii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. Records shall be available on preventive maintenance.

(4) Remedial actions. There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) Personnel available to testify at proceedings. The licensee's testing facility and HHS-certified laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on positive breath analysis or urinalysis results reported by the licensee's testing facility or the HHS-certified laboratory.

(6) Restrictions. The laboratory shall not enter into any relationship with a licensee's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a licensee use a specific MRO.

2.8 Quality Assurance and Quality Control.

(a) General. HHS-certified laboratories and the licensee's testing facility shall have a quality assurance program which encompasses all aspects of the testing process including, but not limited to, specimen acquisition, chain of custody, security, reporting of results, screening and confirmatory testing, and validation of analytical procedures. Quality assurance procedures must be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) Licensee's Testing Facility Quality Control Requirements for Screening Tests. Because all presumptively positive licensee facility screening tests for drugs are forwarded to an HHS-certified laboratory for screening and confirmatory testing when appropriate, the NRC does not require licensees to assess their testing facilities' false positive rates for drugs. To ensure that the rate of false negative tests is kept to the minimum that the immunoassay technology supports, licensees shall perform an immunoassay test on all blind performance test specimens and submit these and a sampling of specimens screened as negative from every test run to the HHS-certified laboratory. The results reported by the certified laboratory must be evaluated and appropriate corrective actions taken. The manufacturer-required performance tests of the breath analysis equipment used by the licensee must be conducted as set forth in the manufacturer's specifications.

(c) Laboratory Quality Control Requirements for Screening Tests at HHS-Certified Laboratories.

(1) Each analytical run of specimens to be screened must include:

- (i) Urine specimens certified to contain no drug;
- (ii) Urine specimens fortified with known standards; and
- (iii) Positive controls with the drug or metabolite at or near the threshold (cut-off).

(2) In addition, with each batch of specimens, a sufficient number of standards must be included to ensure and document the linearity of the assay method over time in the concentration area of the cut-off. After acceptable values are obtained for the known standards, those values will be used to calculate specimen data. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen must be documented. A minimum of 10 percent of all test specimens must be quality control specimens. Laboratory quality control specimens, prepared from spiked urine specimens of determined concentration, must be included in the run and should appear as normal specimens to laboratory analysts. One percent of each run, with a minimum of at least one specimen, must be the laboratory's own quality control specimens.

(d) Laboratory Quality Control Requirements for Confirmation Tests. Each analytical run of specimens to be confirmed shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cut-off).

The linearity and precision of the method shall be periodically documented.

Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(e) Licensee Blind Performance Test Procedures.

(1) Licensees shall only purchase blind quality control materials that:

- (i) Have been certified by immunoassay and GC/MS; and
- (ii) Have stability data which verify performance of those materials over time.

(2) During the initial 90-day period of any contract with an HHS-certified laboratory (not including rewritten or renewed contracts), each licensee shall submit blind performance test specimens to the laboratory within the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 100 specimens) or 30 blind performance test specimens, whichever is greater. Following the initial 90-day period, a minimum of 3 percent of all specimens (to a maximum of 25) or 10 blind performance test specimens, whichever is greater, must be submitted per quarter. Licensees should make an attempt to submit blind performance test specimens during the initial 90-day period and per quarter thereafter at a frequency that corresponds with the submission frequency for other specimens.

(3) Approximately 50 percent of the blind performance test specimens must be blank (i.e., certified to contain no drug) and the remaining specimens must be positive for one or more drugs per specimen in a distribution so that all the drugs for which the licensee is testing are included in approximately equal frequencies of challenge. The positive specimens must be spiked only with those drugs for which the licensee is testing. In addition, 10 percent of the positive blind specimens must be appropriately adulterated or diluted and spiked to between 60 percent and 80 percent of the screening cut-off values established by § 2.7(f) of this appendix, or of any lower cut-off values established by the licensee, to challenge the laboratory's ability to determine specimen validity and perform special processing, as required by § 2.7(e) of this appendix.

(f) Investigation of Errors and Other Matters.

(1) The licensee shall investigate any testing errors or unsatisfactory performance discovered in blind performance testing, in the testing of actual specimens, or through the processing of appeals and MRO reviews, as well as any other errors or matters that could reflect adversely on the integrity of the testing process. The investigation must determine relevant facts and identify the root cause(s) of the testing or process error when possible. The licensee and the laboratory shall take action to correct the cause(s) of any errors or the

unsatisfactory performance that are within their control. A record must be made and retained for a minimum of 3 years of the investigative findings and the corrective action taken, and, where applicable, that record must be dated and signed by the individuals responsible for the day-to-day management and operation of the HHS-certified laboratory. The licensee shall submit to the NRC a report of any incident and action taken or planned within 30 days of completion of the investigation. The NRC shall ensure notification of the finding to HHS.

(2) Should a false positive error occur on a blind performance test specimen or on a regular specimen, the licensee shall promptly notify the NRC. The licensee shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future. If there is reason to believe the error could have been systematic, the licensee may also require review and reanalysis of previously run specimens.

(3) Should a false positive error be determined to be technical or methodological, the licensee shall instruct the laboratory to submit to it all quality control data from the batch of specimens which included any false positive specimen. In addition, the licensee shall require the laboratory to retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting must be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's substance testing program. The licensee and the NRC may require an onsite review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the NRC, HHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

2.9 Reporting and Review of Results

(a) Medical Review Officer shall review results. An essential part of a licensee's testing program is the final review of results. A laboratory confirmed positive test result does not automatically identify a nuclear power plant worker as having used substances in violation of the NRC's regulations or the licensee's company policies. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review must be performed by the MRO before the transmission of results to licensee management officials.

(b) Medical Review Officer--qualifications and responsibilities. The MRO shall be a licensed physician with knowledge of substance abuse disorders. The MRO may be a licensee or contract employee. However, the MRO shall not be an employee or agent of or have any financial interest in a laboratory or a contracted operator of an on-site testing facility whose drug testing results the MRO is reviewing for the licensee. Additionally, the MRO shall not derive any financial benefit by having the licensee use a specific drug testing laboratory or on-site testing facility operating contractor or have any agreement with such parties that may be construed as a potential conflict of interest. The role of the MRO is to review and interpret test results obtained through the licensee's testing program and to identify evidence of subversion of the testing process. The MRO is also responsible for identifying issues associated with the collection and testing of specimens, and advising and assisting management in the planning and oversight of the overall FFD program. In carrying out this responsibility, the MRO shall examine alternate medical explanations for any laboratory confirmed positive test result (this does not include confirmation of blood alcohol levels obtained through the use of a breath alcohol analysis device). This action could include conducting a medical interview with the

individual, review of the individual's medical history, or review of any other relevant biomedical factors. The MRO shall review all medical records made available by the tested individual when a laboratory confirmed positive test could have resulted from legally prescribed medication. The MRO shall not consider the results of tests that are not obtained or processed in accordance with this appendix, although he or she may consider the results of tests on split specimens in making his or her determination, as long as those split specimens have been stored and tested in accordance with the procedures described in this appendix.

(c) Medical Review Officer verification of FFD policy violations.

(1) Before making a final decision to verify a laboratory confirmed positive test result, or other occurrence that would constitute an FFD policy violation (e.g., attempted subversion), the MRO shall give the individual an opportunity to discuss the test result or other occurrence with him or her. Following verification of a laboratory confirmed positive test result or other occurrence as a violation of FFD policy, the MRO shall, as provided in the licensee's policy, immediately notify the applicable EAP and the licensee's management official empowered to recommend or take administrative action (or the official's designated agent). Presumptive positive screening test results must not be reported except as provided by § 26.24(d).

(2) The MRO may verify a laboratory confirmed positive test result, or otherwise make a determination of an FFD policy violation, without having discussed the test result or other occurrence directly with the individual in the following three circumstances:

(i) When the MRO contacts the individual, the individual expressly declines the opportunity to discuss the test result or other occurrence that may constitute an FFD policy violation;

(ii) The MRO, after making all reasonable efforts, has been unable to contact the individual within 14 days of the date on which the MRO receives notice of the laboratory confirmed positive test result, evidence of subversion of the testing process, or other activity that would constitute an FFD policy violation;

(iii) A licensee representative has successfully made and documented contact with the individual and instructed him or her to contact the MRO and more than 5 days have passed since the date the individual was successfully contacted by the licensee representative.

(3) If the MRO makes a determination of an FFD policy violation under the circumstances specified in § 2.9(c) (2) (ii) or (iii), the individual may present to the MRO information documenting that serious illness, injury, or other circumstances unavoidably prevented him or her from being contacted by the MRO or licensee representative or from contacting the MRO in a timely manner. The MRO, on the basis of this information, may reopen the procedure for determination of an FFD policy violation and allow the individual to present information relating to the issue. The MRO may modify the initial determination based on an evaluation of the information provided.

(d) Verification for opiates. Before the MRO verifies a laboratory confirmed positive result as a violation of FFD policy and the licensee takes action for opiates, he or she shall determine that there is reasonable and substantial clinical evidence--in addition to the urine test--of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). Clinical signs of abuse include recent needle tracks or test results that are inconsistent with the ingestion of food or medication including prescription medications containing opiates (e.g., 6-AM test); clinical signs of abuse also include, but are not limited to, behavioral and psychological signs of acute opiate intoxication or withdrawal, or admission of non-prescribed opiate use. This requirement does not apply if the GC/MS confirmation testing for opiates confirms the presence of 6-AM since the presence of this metabolite is proof of heroin use .

(e) Reanalysis authorized. Should any question arise as to the accuracy or validity of a laboratory confirmed positive test result, only the MRO is authorized to order a reanalysis of the original specimen and these retests are authorized only at laboratories certified by HHS. The MRO shall authorize a reanalysis of the original aliquot on timely request (as established by the licensee) by the individual tested, and shall also authorize an analysis of any split specimen stored by or for the licensee under the provisions of § 2.7(k) of this appendix.

(f) Results consistent with responsible substance use. If the MRO determines that there is a legitimate medical explanation for the laboratory confirmed positive test result, and that the use of the substance identified through testing was in the manner and at the dosage prescribed, and the results do not reflect a lack of reliability or trustworthiness, then there has not been a violation of licensee policy. The MRO shall report the test result to the licensee as negative. The MRO shall further evaluate the result and medical explanation to determine if there is a potential risk to public health and safety of the individual being impaired on duty from the substance or from the medical condition. If the MRO determines that such a risk exists, he or she shall conduct a medical determination of fitness.

(g) Medical determination of fitness.

(1) A medical determination of fitness, as defined in § 26.3, must be performed in at least the following circumstances:

(i) When an alternative medical explanation explains the test result but there is a basis for believing impairment on duty could exist, as described in § 2.9(f);

(ii) Before making return-to-duty recommendations subsequent to a worker's removal from duty in accordance with § 26.27(b) or the licensee's FFD policy;

(iii) Before an individual is granted unescorted access when information obtained pursuant to § 26.27(a) shows a history of substance abuse or record of prior FFD violations; and

(iv) If a history of substance abuse is otherwise identified.

(2) (i) If the licensed physician or MRO determines that there is neither conclusive evidence of an FFD policy violation nor a significant basis for concern that the individual may be impaired while on duty, then he or she shall report the result as negative.

(ii) If the licensed physician or MRO determines that there is not conclusive evidence of an FFD policy violation but that there is a significant basis for concern that the individual may be impaired while on duty, then he or she shall report the result as not representing an FFD policy violation but as a condition under which the individual may not be able to safely and competently perform duties. Because these results should not constitute a violation of the licensee's FFD policy or the NRC rule, punitive actions under the rule should not be taken based upon the results. However, the licensed physician, MRO, or the licensee management personnel who are empowered to take appropriate actions shall initiate actions to ensure that any possible limiting condition does not represent a threat to workplace or public health and safety. When deemed appropriate, the matter may also be referred to the EAP.

(h) Result scientifically insufficient. Additionally, the MRO, based on review of inspection reports, quality control data, multiple specimens, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation, the MRO may request reanalysis of the original specimen before making this decision. The MRO may request that reanalysis be performed by the same laboratory, or that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the HHS Guidelines. The licensee's testing facility and the HHS-certified laboratory shall assist in this review process as requested by the MRO by making available the individual(s) responsible for day-to-day management of the

licensee's testing facility, of the HHS-certified laboratory or other individuals who are forensic toxicologists or who have equivalent forensic experience in urine drug testing, to provide specific consultation as required by the licensee. The licensee shall maintain for a minimum of 3 years records that summarize any negative findings based on scientific insufficiency and shall make them available to the NRC on request, but shall not include any personal identifying information in these reports.

Subpart C--Employee Protection

3.1 Protection of Employee Records.

Licensee contracts with HHS certified laboratories and procedures for the licensee's testing facility shall require that test records be maintained in confidence, as provided in § 26.29. Records shall be maintained and used with the highest regard for individual privacy.

Subpart D--Certification of Laboratories Engaged in Chemical Testing

4.1 Use of HHS-Certified Laboratories.

(a) Licensees subject to this part and their contractors shall use only laboratories certified under the HHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs," Subpart C--"Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," (June 9, 1994, 59 FR 29908, 29925-2929) and subsequent amendments thereto for screening and confirmatory testing except for screening tests at a licensee's testing facility conducted in accordance with § 26.24(d). Information concerning the current certification status of laboratories is available from: The Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, Room 815, 5600 Fishers Lane, Rockwall 2 Bldg., Rockville, Maryland 20857.

(b) Licensees or their contractors may use only HHS-certified laboratories that agree to follow the same rigorous chemical testing, quality control, and chain-of-custody procedures when testing for more stringent cut-off levels as may be specified by licensees for the classes of drugs identified in this part, for analysis of whole blood specimens for alcohol, and for any other substances included in licensees' drug panels. Because the HHS national laboratory certification process does not cover practices outside the HHS Guidelines, such as using more stringent cutoff levels than set forth in the HHS Guidelines or testing for additional substances, licensees and their contractors that choose to use practices outside the HHS Guidelines must take measures that are consistent with this part to assure that the reported test results are valid and defensible.

(c) All contracts related to this part between licensees and their contractors and HHS-certified laboratories must require implementation of all obligations of this appendix applicable to HHS-certified laboratories.

Dated at Rockville, Maryland, this _____ day of _____, 2000.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

ATTACHMENT B

TEXT OF RULE

PART 26--FITNESS FOR DUTY PROGRAMS

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APPENDIX A TO PART 26--GUIDELINES FOR DRUG AND ALCOHOL TESTING PROGRAMS

AUTHORITY: Secs. 53, 81, 103, 104, 107, 161, 68 Stat. 930, 935, 936, 937, 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2111, 2112, 2133, 2134, 2137, 2201, 2297f); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

GENERAL PROVISIONS

§ 26.1 Purpose.

This part prescribes requirements and standards for the establishment and maintenance of certain aspects of fitness-for-duty (FFD) programs and procedures by the licensed nuclear power industry, and by licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM).

§ 26.2 Scope.

(a) The regulations in this part apply to licensees authorized to operate a nuclear power reactor, to possess or use formula quantities of SSNM, or to transport formula quantities of SSNM. Each licensee shall implement an FFD program which complies with this part. The provisions of the FFD program must apply to:

- (1) All persons granted unescorted access to nuclear power plant protected areas;
- (2) Licensee, vendor, or contractor personnel required to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures;
- (3) SSNM licensee and transporter personnel who:
 - (i) Are granted unescorted access to Category IA Material;
 - (ii) Create or have access to procedures or records for safeguarding SSNM;
 - (iii) Make measurements of Category IA Material;
 - (iv) Transport or escort Category IA Material; or
 - (v) Guard Category IA Material; and
- (4) FFD program personnel who:
 - (i) Can link test results with the person who was tested prior to determination of an FFD policy violation;
 - (ii) Make medical or management determinations of fitness;
 - (iii) Make removal or return-to-work decisions; or
 - (iv) Are involved in the selection or notification of employees for testing or in the collection or onsite testing of specimens.

(b) The regulations in this part do not apply to NRC employees, to law enforcement personnel, or offsite emergency fire and medical response personnel while responding onsite, or SSNM transporters who are subject to U.S. Department of Transportation drug or alcohol fitness programs that require random testing for drugs and alcohol. The regulations in this part also do not apply to spent fuel storage facility licensees or non-power reactor licensees who possess, use, or transport formula quantities of irradiated SSNM as these materials are exempt from the Category I physical protection requirements as set forth in 10 CFR 73.6.

(c) Certain regulations in this part apply to licensees holding permits to construct a nuclear power plant. Each construction permit holder, with a plant under active construction, shall comply with §§ 26.10, 26.20, 26.23, 26.70, and 26.73 of this part; shall implement a chemical testing program, including random tests; and shall make provisions for employee assistance programs, imposition of sanctions, appeals procedures, the protection of information, and recordkeeping.

(d) The regulations in this part apply to the Corporation required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter only if the Corporation elects to engage in activities involving formula quantities of strategic special

nuclear material. When applicable, the requirements apply only to the Corporation and personnel carrying out the activities specified in § 26.2(a), (3), and (4).

(e) [RESERVED]

(f) Persons performing activities under this part who are covered by a program regulated by another Federal agency or State need be covered by only those elements of a licensee's FFD program not included in the Federal agency or state program as long as all such persons are subject to pre-access (or pre-employment), random, and for-cause urine testing for the drugs specified in the U.S. Department of Health and Human Services (HHS) Mandatory Guidelines and breath testing for alcohol at or below NRC mandated cut-off levels; have their urine specimens tested at a laboratory certified by HHS, the College of American Pathologists or other comparable certification program; have awareness training covering the subjects listed in § 26.21(a)(1), (2), (3), and (5); and access to an impartial and objective procedure for appealing any findings of an FFD violation. Provisions for notification of the licensee(s) granting unescorted access of any FFD violation by the testing agency or organization must be in place.

§ 26.3 Definitions.

Abuse of legal drugs means the use of a legal drug (e.g., alcohol, prescription drugs, over-the-counter drugs) in a manner that constitutes a health or safety hazard to the individual or to others, including on-the-job impairment. Legal or employment actions against an individual for use of legal drugs are presumptive of the abuse of legal drugs.

Aliquot means a portion of a specimen used for testing. It is taken as a sample representing the whole specimen.

Behavioral observation means observation by supervisors in the course of their contacts with other personnel to detect degradations in performance, signs of impairment, or changes in behavior that may indicate the need to evaluate an individual's fitness for duty.

Blood Alcohol Concentration (BAC) means a measure for determining the mass of alcohol in a volume of blood.

Category IA Material means strategic special nuclear material (SSNM) directly useable in the manufacture of a nuclear explosive device, except if:

(1) The dimensions are large enough (at least 2 meters in one dimension, greater than 1 meter in each of two dimensions, or greater than 25 cm in each of three dimensions) to preclude hiding the item on an individual;

(2) The total weight of 5 formula kilograms of SSNM plus its matrix (at least 50 kilograms) cannot be carried inconspicuously by one person; or

(3) The quantity of SSNM (less than 0.05 formula kilogram) in each container requires protracted diversions in order to accumulate 5 formula kilograms.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Confirmatory test means a second analytical procedure to identify the presence of a specific drug or drug metabolite which is independent of the screening test and which uses a different technique and chemical principle from that of the screening test in order to ensure reliability and accuracy. (At this time, gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.) For determining blood alcohol concentration levels, a "confirmatory test" means a second test using another breath alcohol analysis device. Additional information may be obtained by gas chromatography analysis of blood.

Confirmed positive test means a laboratory confirmed positive test result that has been verified as a violation of FFD policy by the Medical Review Officer (MRO) after evaluation. A "confirmed positive test" for alcohol is obtained as a result of a confirmation of blood alcohol concentration (BAC) levels of 0.04 percent or higher or a BAC of 0.02 percent or higher after an individual has been in a work status for two (2) or more hours or a BAC of 0.03 percent or higher after an individual has been in a work status for more than one (1) hour with a second breath analysis without MRO evaluation.

Contractor means any company or individual with which the licensee has contracted for work or service to be performed inside the protected area boundary, either by contract, purchase order, or verbal agreement.

Custody-and-control form means the form used to document the maintenance of the chain of custody for specimens. (Licensees that test urine specimens for only the five drugs specified in Appendix A to Part 26 and at the cut-off levels prescribed in the HHS Mandatory Guidelines can use the Federal Drug Testing Custody and Control Form (OMB Number 0930-0158). However, this form cannot be used by licensees testing for additional drugs, testing at lower cut-off levels, or when testing blood specimens. Those licensees should use a "look alike" form that accomplishes the same specimen security and accountability tracking purposes.)

Cut-off level means the value set for designating a test result as positive.

HHS-certified laboratory means a laboratory that is certified to perform urine drug testing under the Department of Health and Human Services "Mandatory Guidelines for Federal Workplace Drug Testing Programs," June 9, 1994, (59 FR 29908), and all revisions thereto.

History of substance abuse means having violated an FFD policy and been removed from activities covered by this part at any time, or, during the past 5 years, having (i) used, sold, or possessed illegal drugs; (ii) abused legal drugs; (iii) subverted or attempted to subvert a drug or alcohol testing program; (iv) refused to take a drug or alcohol test; (v) been subjected to a plan for substance abuse treatment (except for self-referral); or (vi) had any legal or employment action taken for alcohol or drug use.

Illegal drugs means those drugs included in Schedules I through V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

Laboratory confirmed positive means the result of a confirmatory test that has established the presence of drugs, or drug metabolites, at a sufficient level to be an indication of prohibited drug use.

Licensee's testing facility means a drug testing facility operated by a licensee or one of its vendors or contractors to perform onsite screening testing of urine specimens.

Medical determination of fitness means the process whereby a licensed physician, who may be the Medical Review Officer, qualified to make such determination examines and interviews an individual and reviews any appropriate and relevant medical records, in accordance with standard clinical procedures, to determine whether there are indications that the individual may be in violation of the licensee's FFD policy or is otherwise unable to safely and competently perform duties. The qualifications for making the determination are related to the fitness issues presented by the patient.

Medical Review Officer means a licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Presumptive positive screening test result means the result of a screening test for drugs and drug metabolites that indicates the presence of some drug or drug metabolite and that has the potential to be confirmed through gas chromatography/mass spectrometry testing by an HHS-certified laboratory as a laboratory confirmed positive test result, or the result of a screening test for alcohol indicating a BAC of 0.02 percent or greater.

Protected area has the same meaning as in § 73.2(g) of this chapter, an area encompassed by physical barriers and to which access is controlled.

Screening test means an immunoassay screen for drugs or drug metabolites that may be used to eliminate "negative" urine specimens from further consideration or the first breathalyzer test for alcohol.

SSNM means Strategic Special Nuclear Material.

Substance abuse means the use, sale, or possession of illegal drugs or the abuse of legal drugs or other substances.

Subversion and Subvert the testing process mean an act intended to avoid being tested or to bring about an inaccurate drug or alcohol test result for oneself or others. Acts of subversion can occur at any stage of the testing program including selection and notification of individuals for testing, specimen collection, specimen analysis, and testing result reporting processes, and can include providing a surrogate urine specimen, diluting a specimen (in vivo or in vitro), and adding an adulterant to a specimen.

Supervisor means any person who has the authority or immediate oversight responsibilities to direct or control activities of any other person or persons within the protected area or has ongoing responsibility for the supervision of an individual with unescorted access status while that individual is not in the protected area.

Transporter means a general licensee pursuant to 10 CFR 70.20a, who is authorized to possess formula quantities of Strategic Special Nuclear Material as defined in 10 CFR 73.2 in the regular course of carriage for another or storage incident thereto, and includes the driver or operator of any conveyance, and the accompanying guards or escorts.

Vendor means any company or individual, not under contract to a licensee, providing services in protected areas.

§ 26.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 26.6 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. Any exemptions submitted under this part must meet the provisions of § 50.12 or §70.14, as applicable.

§ 26.7 Communications

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part must be addressed to the NRC Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Copies of all communications must be sent to the appropriate regional office and resident inspector. Communications and reports may be delivered in person at the Commission's offices L S at 11555 Rockville Pike, One White Flint North, Rockville, Maryland, or at the Commission's Public Document Room located at 2120 L Street, NW (Lower Level), Washington, DC.

§ 26.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). OMB has approved the information collection requirements contained in this part under control number 3150-0146.

(b) The approved information collection requirements contained in this part appear in §§ 26.6, 26.20, 26.21, 26.22, 26.23, 26.24, 26.27, 26.28, 26.29, 26.70, 26.71, 26.73, 26.80, and Appendix A.

GENERAL PERFORMANCE OBJECTIVES

§ 26.10 General performance objectives.

Fitness-for-duty programs must:

(a) Provide reasonable assurance that nuclear power plant personnel, transporter personnel, and personnel of licensees authorized to possess or use formula quantities of SSNM, will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties; and

(b) Provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of this part.

PROGRAM ELEMENTS AND PROCEDURES

§ 26.20 Written policy and procedures.

Each licensee subject to this part shall establish and implement written policies and procedures designed to meet the general performance objectives and specific requirements of this part. Each licensee shall retain a copy of its latest written policy and procedures as a record until the Commission terminates the licenses for which the policy and procedures were developed. If any portion of the policies and procedures are superseded, the superseded material must be retained for at least 3 years. As a minimum, written policies and procedures must address fitness for duty through the following:

(a) An overall description of licensee policy on fitness for duty. The policy must address use of and offsite involvement with illegal drugs, abuse of legal drugs, subversion of the testing process, and refusals to provide a specimen for testing. A clear and concise written statement of this policy must be prepared and be in sufficient detail to provide affected individuals with

information on what is expected of them, and what consequences may result from lack of adherence to the policy. This statement must be readily available to all persons subject to the policy.

- (1) As a minimum, the written policy must prohibit the consumption of alcohol--
 - (i) Within an abstinence period of at least 5 hours preceding any scheduled working tour, and
 - (ii) During the period of any working tour.
- (2) Licensee policy should also address other factors that could affect fitness for duty such as mental stress, fatigue, illness, and the use of prescription and over-the-counter medications that could cause impairment.
- (b) A description of programs which are available to personnel desiring assistance in dealing with drug, alcohol, or other problems that could adversely affect the performance of activities within the scope of this part.
- (c) Procedures to be used in testing for drugs and alcohol, including procedures for protecting individuals providing a specimen and the integrity of the specimen, and the quality controls used to ensure the test results are valid and attributable to the correct individual.
- (d) A description of immediate and follow-on actions which will be taken, and the procedures to be used, in those cases where persons who are employed by licensees, vendors, or contractors, and are assigned to duties within the scope of this part, are determined to have--
 - (1) Been involved in the use, sale, or possession of illegal drugs;
 - (2) Consumed alcohol during the mandatory pre-work abstinence period, while on duty, or to excess before reporting to duty as demonstrated with a test that can be used to determine blood alcohol concentration;
 - (3) Attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means; or
 - (4) Refused to provide a specimen for analysis.
- (e) A procedure that will ensure that persons called in to perform an unscheduled working tour are fit to perform the task assigned. As a minimum, this procedure must--
 - (1) Require a statement to be made by a called-in person as to whether he or she considers himself or herself fit to perform the task assigned and whether he or she has consumed alcohol within the length of time stated in the pre-duty abstinence policy;
 - (2) If alcohol has been consumed within this period and the person is called in, require a determination of fitness for duty by breath analysis or other means (collection of urine under § 26.24(a)(3) is not required); and
 - (3) Require the establishment of controls and conditions under which a person who has been called-in can perform work, if necessary, although alcohol has been consumed. Consumption of alcohol during the abstinence period shall not by itself preclude a licensee from using individuals needed to respond to an emergency.
- (f) Licensees seeking to grant unescorted access pursuant to 10 CFR 73.56 to personnel covered by another licensee's FFD program that complies with this part may credit that licensee's program through verification that the individual is currently and will continue to be subject to the random testing and behavioral observation programs of either his or her employer or those of the host licensee.

§ 26.21 Policy communications and awareness training.

- (a) Persons assigned to activities within the scope of this part must be provided with appropriate training to ensure that they understand--

- (1) Licensee policy and procedures, including the methods that will be used to implement the policy;
 - (2) The personal and public health and safety hazards associated with the use of illegal drugs and the abuse of legal drugs including alcohol;
 - (3) The effect of prescription and over-the-counter drugs and dietary conditions on job performance and on chemical test results, and the role of the MRO;
 - (4) Employee assistance programs provided by the licensee; and
 - (5) What is expected of them and what consequences may result from lack of adherence to the policy,
- (b) Initial training in the five topics in paragraph (a) of this section must be completed before assignment to activities within the scope of this part. Refresher training in those five topics must be completed on a nominal 24-month frequency or more frequently where the need is indicated. A record of the training must be retained for a period of at least 3 years. Licensees may accept training of individuals who have been subject to another part 26 program and who have had initial or refresher training within the 24 months before assignment provided that training by the accepting licensee in the site-specific topics covered by paragraphs (a) (1), (4), and (5) of this section is completed before the assignment to duties within the scope of this part.

§ 26.22 Training of supervisors and escorts.

- (a) Managers and supervisors of activities within the scope of this part must be provided appropriate training to ensure that they understand--
- (1) Their role and responsibilities in implementing the program;
 - (2) The roles and responsibilities of others, such as the personnel, medical, and employee assistance program staffs;
 - (3) Techniques for recognizing drugs and indications of the use, sale, or possession of drugs;
 - (4) Behavioral observation techniques for detecting degradation in performance, impairment, or changes in an individual's behavior; and
 - (5) Procedures for initiating appropriate corrective action, to include referral to the employee assistance program.
- (b) Persons assigned to escort duties shall be provided appropriate training in techniques for recognizing drugs and indications of the use, sale, or possession of drugs, techniques for recognizing aberrant behavior, and the procedures for reporting problems to supervisory or security personnel.
- (c) Initial training for escorts and supervisors employed by licensees must be completed before assignment of duties within the scope of this part, except that for an employee's first assignment to supervisory duties within the scope of this part, the initial training must be completed as soon as feasible but no later than 3 months following this assignment. Initial training for supervisors employed by contractors must be completed before their assignment to duties within the scope of this part or within 10 days after the first assignment to on-site supervisory duties within the scope of this part. Refresher training must be completed on a nominal 12-month frequency, or more frequently where the need is indicated. A written examination on the training material given on a nominal 12-month frequency may be used in lieu of refresher training for escorts and supervisors employed by licensees. The written examination must require a demonstration of adequate knowledge of the areas covered in paragraph (a) of this section. Refresher training for escorts and supervisors employed by

licensees must be completed on a nominal 36-month frequency even if examinations are used to fulfill this requirement during the interim period. A record of the training or examination in lieu of training must be retained for a period of at least 3 years. Licensees may accept training of individuals who have been subject to a part 26 program and who have had initial or refresher training within the 12 months before assignment, provided that training by the accepting licensee in the topics covered by paragraphs (a) (1), (2), and (5) of this section is completed before assignment to duties within the scope of this part.

§ 26.23 Contractors and vendors.

(a) All contractor and vendor personnel performing activities within the scope of this part for a licensee must be subject to either the licensee's program relating to fitness for duty, or to a program, formally reviewed and approved by the licensee, which meets the requirements of this part. Written agreements between licensees and contractors or vendors for activities within the scope of this part must be retained for the life of the contract and will clearly show that--

(1) The contractor or vendor is responsible to the licensee for adhering to the licensee's fitness-for-duty policy, or maintaining and adhering to an effective fitness-for-duty program, which meets the standards of this part; and

(2) Personnel with a known history of substance abuse or having been denied access or removed from activities within the scope of this part at any nuclear power plant for violations of an FFD policy will not be assigned to work within the scope of this part without the knowledge and consent of the licensee.

(b) Each licensee subject to this part shall assure that contractors whose own fitness-for-duty programs are relied on by the licensee adhere to an effective program, which meets the requirements of this part, and shall conduct audits pursuant to § 26.80 for this purpose.

§ 26.24 Chemical and alcohol testing.

(a) To provide a means to deter and detect substance abuse, the licensee shall implement the following chemical testing programs for persons subject to this part:

(1) (i) Pre-access testing for drugs and alcohol must be conducted within 60 days before the granting of unescorted access to protected areas or assignment to activities within the scope of this part unless the individual:

(A) Has been covered by a program meeting the requirements of this part for at least 30 days during the 60 days immediately previous to the granting of unescorted access, and

(B) Has no history of substance abuse.

(ii) Any negative drug and alcohol test meeting the standards of this part and performed within 60 days before granting unescorted access may serve as the pre-access test. A negative test result must be obtained before the granting of unescorted access unless the individual has no history of substance abuse and has either had a negative test result on a test meeting the standards of this part performed within 6 months before granting unescorted access or has been covered by a program meeting the standards of this part for 2 consecutive weeks during that period.

(2) Random drug and alcohol testing must be unannounced and imposed in a statistically random and unpredictable manner so that all persons in the population subject to testing have an approximately equal probability of being selected and tested. Random testing must include testing during all types of work periods, including weekends, backshifts, and

holidays. The tests must be administered so that a person completing a test is immediately eligible for another unannounced test. At a minimum, random tests must be administered on a nominal weekly frequency and at various times during the day. Reasonable efforts must be made to test persons selected for random testing. Persons off site when selected for testing, and not reasonably available for testing in a timely manner, must be tested at the earliest reasonable and practical opportunity and without notification to the individual until immediately prior to his or her reporting for the test. These tests will also fulfill any return-to-duty testing required for these persons, and must be reported to the NRC as random tests. Random testing must be conducted at an annual rate equal to at least 50 percent of the workforce.

(3)(i) For-cause drug and alcohol testing must be conducted:

(A) Following any observed behavior or physical condition that creates a reasonable suspicion of possible substance abuse;

(B) After accidents involving a failure in individual performance resulting in personal injury, in a radiation exposure or release of radioactivity in excess of regulatory limits, or in actual or potential substantial degradations of the level of safety of the plant if there is reasonable suspicion that the individual's performance contributed to the event; and

(C) After receiving credible information that an individual is abusing drugs or alcohol.

(ii) The individual's unescorted access status must be suspended until the individual is pronounced fit for duty based on a management and medical determination of fitness, except for those instances where an individual tests negative in a for-cause test. If the test is based on suspected use of alcohol and the breath analysis is negative, the individual, if determined fit for duty by a management determination of fitness, may be returned to duty pending results of urinalysis for drugs. For-cause drug and alcohol testing must be conducted as soon as practicable after the occurrence of the event. Except under documented unusual circumstances, such testing must be conducted within no more than 2 hours for an alcohol test and 8 hours for specimen collection for a drug test.

(4) Follow-up testing must be conducted on an unannounced and unpredictable basis to verify continued abstention from the use of substances as covered under this part. An individual must be subject to follow-up testing that is tailored to the individual's medical history, but not less frequently than once every 30 days for 4 months after unescorted access is reinstated and at least once every 90 days for the next 2 years and 8 months if:

(i) unescorted access was reinstated for that individual after a suspension under § 26.27(b)(3), or

(ii) unescorted access will be reinstated for that individual after removal under § 26.27(b)(3), (b)(4), or (c)

(5) Return-to-duty testing must be conducted when a person seeks to regain unescorted access to protected areas of the site in question after an absence from the possibility of being tested under that site licensee's program for more than 60 days or when a person seeks to regain unescorted access after having been denied access under the provisions of § 26.27(b). Any negative drug and alcohol test meeting the standards of this part and performed within 60 days before the granting of unescorted access may serve as the return-to-duty test except in the case of those who have been denied access under the provisions of § 26.27(b). A negative test result must be obtained before the granting of unescorted access unless the individual has no history of substance abuse and either has had a negative test result on a test meeting the standards of this part performed within 6 months before the reinstatement of unescorted access or has been covered by a program meeting the standards of this part for 2 consecutive weeks during that period.

(b) Testing for drugs and alcohol, at a minimum, must conform to the "Guidelines for Drug and Alcohol Testing Programs," issued by the NRC and appearing in Appendix A to this part, hereinafter referred to as the NRC Guidelines. Licensees, at their discretion, may implement programs with more stringent standards (e.g., lower cut-off levels, broader panel of drugs). All requirements in this part still apply to persons who fail a more stringent standard, but do not test positive under the NRC Guidelines. Management actions must be the same with the more stringent standards as if the individual had failed the NRC standards.

(c) Licensees shall test specimens collected under each type of test listed in § 26.24(a) for all substances described in § 2.1(a) of the NRC Guidelines (Appendix A to part 26). In addition, licensees may consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other substances with abuse potential are being used in the geographical locale of the facility and the local workforce. When appropriate, other substances so identified may be added to the panel of substances for testing. Appropriate cut-off limits must be established by the licensee for these substances.

(d)(1) All collected urine and blood specimens must be forwarded to a laboratory certified by HHS, except that licensees may conduct screening tests of urine aliquots to determine which specimens are negative and need no further testing, provided the licensee's staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for the testing are implemented. All such testing of specimens must include tests to ensure specimen validity as required by § 2.7(e) of Appendix A to part 26. Quality control procedures for screening tests by a licensee's testing facility must include the processing of blind performance test specimens and the submission to the HHS-certified laboratory of a sampling of specimens initially analyzed as negative. Except for the purposes discussed in § 26.24(d)(2), access to the results of the above screening tests must be limited to the licensee's testing staff, the MRO, the FFD Program Manager, and the employee assistance program staff, when appropriate.

(2) An individual may not be removed or temporarily suspended from unescorted access or be subjected to other administrative action based solely on a presumptive positive screening test result from any drug test, other than for marijuana or cocaine metabolites, unless other evidence, including information obtained under the process set forth in § 2.7(e) of appendix A indicates that the individual is impaired or might otherwise pose a safety hazard. With respect to onsite screening tests for marijuana and cocaine metabolites, licensee management may be informed and licensees may temporarily suspend individuals from unescorted access or from normal duties or take lesser administrative actions against the individual based on a presumptive positive screening test result provided the licensee complies with the following conditions:

(i) For the drug for which action will be taken, at least 85 percent of the specimens which were determined to be presumptively positive as a result of onsite screening tests during the last 12-month data reporting period submitted to the Commission under § 26.71(d) were subsequently reported as positive by the HHS-certified laboratory as the result of a GC/MS confirmatory test.

(ii) There is no loss of compensation or benefits to the tested person during the period of temporary administrative action.

(iii) Immediately upon receipt of a negative report from the HHS-certified laboratory, any matter which could link the individual to a temporary suspension is eliminated from the tested individual's personnel record or other records.

(iv) No disclosure of the temporary removal or suspension of, or other administrative action against, an individual whose test is not subsequently confirmed as a violation of FFD

policy may be made in response to a suitable inquiry conducted under the provisions of § 26.27(a), a background investigation conducted under the provisions of § 73.56, or to any other inquiry or investigation. For the purpose of assuring that no records have been retained, access to the system of files and records must be provided to licensee personnel conducting appeal reviews, inquiries into an allegation, or audits under the provisions of § 26.80, or to an NRC inspector or other Federal officials. The tested individual must be provided a statement that the records specified in paragraph (d)(2)(iii) of this section have not been retained and must be informed in writing that the temporary removal or suspension or other administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for information concerning removals, suspensions, administrative actions or history of substance abuse.

(e) The period of time allowed between the notification of the individual and the actual collection of a specimen must be kept at a minimum consistent with operational constraints. Whenever practicable, the individual should not be allowed the time or opportunity to obtain materials or take any action that would subvert the testing process or the test results.

(f) The MRO shall complete the review of test results reported by the HHS-certified laboratory and notify licensee management as soon as practicable. The MRO shall report all determinations of violations of the licensee's FFD policy to management in writing and in a manner designed to ensure confidentiality of the information. To assure that action is taken immediately, provisions must be made to ensure that the MRO is able to contact appropriate licensee management at any time. Should the MRO's review not be completed within 14 days of the collection of a specimen, licensee management must be advised of available test results, the status of the review, the reasons for the delay, and appropriate recommendations.

(g) All testing of urine specimens for drugs, except screening tests performed by licensees under paragraph (d) of this section, must be performed in a laboratory certified by HHS for that purpose consistent with its standards and procedures for certification. Except for suspect specimens submitted for special processing (§ 2.7(d) or (e) of Appendix A to part 26), all specimens sent to HHS-certified laboratories must be subject to screening analysis by the laboratory and all specimens screened as presumptively positive must be subject to confirmatory testing by gas chromatography/mass spectroscopy analysis by the laboratory. Licensees shall submit blind performance test specimens to HHS-certified laboratories in accordance with the NRC Guidelines (Appendix A to part 26). Licensees shall ensure that all collected specimens are tested and that laboratories report results for all specimens sent for testing, including blind performance test specimens.

(h) Tests for alcohol must be administered by breath analysis using breath alcohol analysis devices meeting evidential standards described in § 2.7(p)(3) of Appendix A to part 26. If the screening test shows a blood alcohol concentration (BAC) of 0.02 percent or greater, a confirmatory test for alcohol must be performed using another breath alcohol analysis device. A confirmatory test for alcohol indicating a BAC of 0.04 percent or greater must be declared a positive test. A confirmatory test result showing a BAC of 0.02 percent or greater after the individual has been in a work status (including any breaks for rest, lunch, dental/mental appointments, etc.) for two (2) or more hours or a BAC of 0.03 percent or greater after an individual has been in a work status for more than one (1) hour must also be declared a positive test. Further testing for alcohol must be through analysis of blood specimens, and must only be administered if requested by the individual for the purposes of obtaining additional information that could be considered during an appeal pursuant to § 26.28. Such a test must be a gas chromatography analysis of whole blood performed on a blood specimen drawn as soon as possible after the confirmatory breath analysis. Any alcohol in the blood specimen may be

considered together with the elapsed time between the confirmatory test and the collection of the blood specimen.

(i) If an individual has a medical condition that makes collection of breath, blood, or urine specimens difficult or hazardous, the MRO, in consultation with the treating or personal physician, may authorize an alternative evaluation process, tailored to the individual case, for determining whether a violation of FFD policy has occurred, provided this process includes measures to prevent subversion and can achieve results comparable to those produced by urinalysis for illegal drugs and breath analysis for alcohol.

§ 26.25 Employee assistance programs (EAP).

Each licensee subject to this part shall maintain an EAP program to strengthen FFD programs by offering assessment, short-term counseling, referral services, and treatment monitoring to employees with problems that could adversely affect the performance of activities within the scope of this part. Employee assistance programs must be designed to achieve early intervention. The EAP must also provide for confidential assistance except that the EAP staff shall inform licensee management when a determination has been made that any individual's condition constitutes a hazard to himself or herself or others (including those who have self-referred).

§ 26.27 Management actions and sanctions to be imposed.

(a)(1) (i) Before assigning an individual to activities within the scope of this part, as described in § 26.2(a), the licensee shall obtain a written statement from the individual as to whether he or she:

(A) Has in the past 5 years used, sold, or possessed any illegal drugs, or had a legal or employment action taken against him or her for alcohol or drug use;

(B) Has in the past 5 years been determined to have violated an FFD policy, or as a result of action taken in accordance with an FFD policy been denied initial assignment to activities within the scope of this part as described in § 26.2(a), or has been subject to a plan for treating substance abuse (except for self-referral for treatment); or

(C) Has at any time as a result of action taken in accordance with an FFD policy been removed from activities within the scope of this part as described in § 26.2(a).

(ii) Power reactor licensees need not obtain statements responding to the activities listed in § 26.2(a)(3) unless the background investigation conducted in accordance with 10 CFR 73.56 indicates the person was previously employed by a licensee authorized to possess or transport Category I nuclear material.

(2) The statement made under paragraph (a)(1) of this section must include the individual's declaration as to the specific type, duration, and resolution of any such matter.

(3) The licensee shall complete a suitable inquiry on a best-efforts basis to verify the accuracy of the individual's written statement made under paragraphs (a) (1) and (a) (2) of this section. This suitable inquiry should cover at least the past 5 years but in no case less than the past 3 years.

(4) If a record of the type described in paragraphs (a) (1), (2), and (3) of this section is established which raises a concern about the person's history of alcohol or drug use, the new assignment to activities within the scope of this part or granting of unescorted access must be based upon a management and medical determination of fitness for duty and the establishment of an appropriate follow-up testing program, as specified in § 26.24(a)(4). The restrictions of

paragraph (b) of this section must be observed; these restrictions include return-to-duty testing, determination of fitness, and proof of abstinence. To meet the suitable inquiry requirement, the identity of persons denied unescorted access or removed under the provisions of this part and the circumstances for the denial or removal, including test results, will be made available in response to a licensee's, contractor's, or vendor's inquiry supported by a release signed by the individual being investigated that authorizes the disclosure of the information.

(5) Failure by an individual to list reasons for removal or revocation of unescorted access or failure to authorize the release of information is sufficient cause for denial of unescorted access.

(6) Where temporary unescorted access pursuant to 10 CFR 73.56 is to be granted to an individual, the requirements in this paragraph must also be satisfied before such access is provided:

(i) If the individual has not previously been removed for violating a licensee's FFD policy, the licensee must either comply with the requirements of this section for full unescorted access or complete a suitable inquiry to verify the accuracy of the individual's written statement obtained under paragraphs (a) (1) and (a) (2) of this section covering the past year's activities (or document its best efforts in this regard), initiate a suitable inquiry for the balance of the past 5 years, and administer a drug and alcohol test in accordance with the requirements of § 26.24(a)(1). In making the suitable inquiry covering the past year's activities, the licensee may use information received over the telephone if a record of the contents of the telephone call is made and retained, or information received by electronic means such as facsimile or e-mail is retained.

(ii) If the individual has been previously removed for violating a licensee's FFD policy, the temporary access provisions of 10 CFR 73.56 are not applicable and cannot be utilized.

(7) If an individual is returning to a licensee after an absence from the possibility of being tested under that site licensee's program for more than 60 days, the licensee must complete a suitable inquiry not later than 72 hours after unescorted access has been restored to ascertain if there were any substance abuse or other violation of an FFD policy during the absence, and must assure that the requirements for testing in accordance with § 26.24(a)(5) have been satisfied. In making the suitable inquiry, the licensee may use information received over the telephone if a record of the contents of the telephone call is made and retained, or information received by electronic means such as facsimile or e-mail is retained.

(b) Each licensee subject to this part shall, at a minimum, take the following actions. The requirements of this paragraph do not prohibit the licensee from taking more stringent action.

(1) Personnel, including applicants, who are impaired, those whose fitness may be questionable, and those determined to have violated the licensee's FFD policy shall be immediately denied unescorted access or otherwise removed from activities within the scope of this part. These persons may be assigned to or returned to their duties only after impairing or questionable conditions are resolved and the individual is determined to be fit to safely and competently perform activities within the scope of this part by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24(a)(5) must be conducted before the individual may be returned to duty and, when applicable, follow-up testing under § 26.24(a)(4) must be conducted to verify continued abstinence from the use of substances.

(2) Lacking any other evidence to indicate the use, sale, or possession of illegal drugs or use of alcohol on site, the following must be presumed to be an indication of offsite drug or alcohol use in violation of the company FFD policy:

(i) A laboratory confirmed positive test result that is verified by the MRO as a policy violation; or

(ii) A confirmatory breath test for alcohol that indicates the individual had a BAC that violated the standards established in § 26.24(h) during any scheduled working tour.

(3) The first violation of the FFD policy involving a confirmed positive drug or alcohol determination must, at a minimum, result in immediate removal from activities within the scope of this part for at least 14 days and referral to the EAP for assessment and counseling during any suspension period. If the individual is retained by the licensee in an employment status pending reinstatement of unescorted access, plans for treatment, follow-up, and future employment, if applicable, must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period. Such individuals must continue to be covered during any suspension period by the applicable FFD program with respect to behavioral observation if in a work status, chemical testing, and sanctions for violations of the licensee's FFD policy. Before an individual is permitted to be returned to duty or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform such activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24(a)(5) must be conducted before the individual may be returned to duty and follow-up testing under § 26.24(a)(4) must be conducted to verify continued abstinence from the use of substances. Any subsequent violation of FFD policy, including during an assessment or treatment period, must immediately result in revocation of authorization to perform activities described in § 26.2(a) for a minimum of 3 years from the date of removal.

(4) Any individual determined to have been involved in the sale, use, or possession of illegal drugs or the use of alcohol while, as applicable, within a protected area of any nuclear power plant, within a facility that is licensed to possess or use SSNM, or within a transporter's facility or vehicle, must immediately have his or her authorization to perform activities within the scope of this part as described in § 26.2(a) revoked for a minimum of 5 years from the date of revocation.

(5) Persons removed for periods of 3 years or more under the provisions of paragraphs (b)(2), (b)(3), (b)(4), and (c) of this section and who would have been removed under the current standards of a hiring licensee, may be granted unescorted access and assigned duties within the scope of this part by a licensee subject to this part only when the hiring licensee receives satisfactory medical assurance that the person has abstained from the use of illegal drugs and the abuse of legal drugs for at least 3 years. Before an individual is permitted to be returned or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform these activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24(a)(5) must be conducted before the individual may be assigned duties and follow-up testing under § 26.24(a)(4) must be conducted to verify continued abstinence from the abuse of substances. Any further violation of FFD policy must immediately result in permanent revocation of authorization to perform activities described in § 26.2(a).

(6) Paragraphs (b)(3), (4), and (5) of this section do not apply to the misuse of valid prescription or over-the-counter drugs. Licensee sanctions for confirmed misuse of valid prescription and over-the-counter drugs must be sufficient to deter abuse of legally obtainable substances a substitute for abuse of proscribed drugs.

(c) Any act or attempted act to subvert the testing process, including refusal to provide a specimen for testing, must be a violation of the licensee's FFD policy and must result in

revocation of authorization to perform activities described in § 26.2(a) for a minimum of 3 years. Any act or attempted act to subvert the testing process, or resignation before removal for violation of company FFD policy concerning drugs and alcohol must be recorded and provided in response to a suitable inquiry. The specific cause for a removal, e.g., that a laboratory confirmed positive test result was obtained and that the individual resigned before an MRO review, must also be provided in response to a suitable inquiry. A record of these actions must be retained consistent with § 26.71(c) following any revocation of authorization to perform activities described in § 26.2(a).

(d) If a licensee has a reasonable belief that an NRC employee or NRC contractor may be under the influence of any substance, or otherwise unfit for duty, the licensee may not deny access but shall escort the individual. In any instance of this occurrence, the appropriate Regional Administrator must be notified immediately by telephone. During other than normal working hours, the NRC Operations Center must be notified.

§ 26.28 Appeals.

Each licensee subject to this part, and each contractor or vendor implementing an FFD program under the provisions of § 26.23, shall establish a procedure for licensee and contractor or vendor employees and applicants for unescorted access to appeal a determination of a violation of FFD policy. The procedure must provide notice to the individual of the grounds for the determination of a violation of FFD policy, and must provide an opportunity to respond and to submit additional relevant information. The procedure must provide for an objective, impartial review of the facts relating to the determination of a violation of FFD policy. The review must be conducted by persons not associated with the administration of the FFD program, as described in § 26.2(a)(4), and may include internal management. If the appeal is successful, the relevant records must be corrected. A licensee review procedure need not be provided to employees of contractors or vendors when the contractor or vendor is administering its own alcohol and drug testing.

§ 26.29 Protection of information.

(a) Each licensee subject to this part, that collects personal information on an individual for the purpose of complying with this part, shall establish and maintain a system of files and procedures for the protection of the personal information. This system must be maintained until the Commission terminates each license for which the system was developed.

(b) Licensees, contractors, and vendors may not disclose the personal information collected and maintained to persons other than assigned Medical Review Officers, other licensees, contractors or vendors, or their authorized representatives legitimately seeking the information as required by this part for unescorted access decisions and who have obtained a release from current or prospective employees or contractor personnel, NRC representatives, appropriate law enforcement officials under court order, the subject individual or his or her representative designated in writing for specified FFD matters by the subject individual, to those licensee representatives who have a need to have access to the information in performing assigned duties, including medical determinations of fitness and audits of licensee, contractor, and vendor programs, to the presiding officer in a judicial or administrative proceeding initiated by the subject individual, to persons deciding matters on review or appeal, and to other persons pursuant to court order. This section does not authorize the licensee, contractor, or vendor to withhold evidence of criminal conduct from law enforcement officials.

(c) Upon receipt of a written request by the subject individual, the licensee, contractor, or vendor possessing such records shall promptly provide copies of all records pertaining to the determination of a violation of the licensee's FFD policy, including test results, MRO reviews, and management determinations of results pertaining to the subject individual. Records relating to the results of any relevant laboratory certification review or revocation of certification proceeding shall be obtained from the relevant laboratory and provided to the subject individual upon request.

INSPECTIONS, RECORDS, AND REPORTS

§ 26.70 Inspections.

(a) Each licensee subject to this part and their contractors and vendors shall permit duly authorized representatives of the Commission to inspect, copy, or take away copies of its records and inspect its premises, activities, and personnel as may be necessary to accomplish the purposes of this part.

(b) Written agreements between licensees and their contractors and vendors must clearly show that the--

(1) Licensee is responsible to the Commission for maintaining an effective fitness-for-duty program in accordance with this part; and

(2) Duly authorized representatives of the Commission may inspect, copy, or take away copies of any licensee, contractor, or vendor documents, records, and reports related to implementation of the licensee, contractor, or vendor FFD program under the scope of the contracted activities. This includes documents, records, and reports of FFD service contractors (e.g., contracted HHS-certified laboratory, MRO, EAP, and specimen collection services) related to licensee, contractor, or vendor FFD programs.

§ 26.71 Recordkeeping requirements.

Each licensee subject to this part and each contractor and vendor implementing a licensee approved program under the provisions of § 26.23 shall--

(a) Retain records of inquiries conducted in accordance with § 26.27(a), that result in the granting of unescorted access to protected areas, until 5 years following termination of such access authorizations;

(b) Retain records pertaining to the determination of a violation of the FFD policy and the related personnel actions for a period of at least 5 years or until completion of all legal proceedings related to the violation, whichever is later;

(c) Retain records pertaining to the determination of a violation of the FFD policy of persons whose authorization to perform activities within the scope of this part has been revoked under § 26.27(b)(3), (4), (5) or (c), until the Commission terminates each license under which the records were created; and

(d) Collect and compile FFD program performance data on a standard form and submit the data to the Commission either for a calendar year period (January 1 through December 31) or a 6-month period (January through June, and July through December) by no later than 60 days after the end of the reporting period. The data for each site (corporate and other support staff locations may be separately consolidated) must include: random testing rate; drugs tested for and cut-off levels, including results of tests using lower cut-off levels and tests for other drugs; workforce populations tested; numbers of tests and results by population, and type of

test (i.e., pre-access, random, for-cause, etc.); substances identified; summary of management actions; number of subversion attempts by type; and a list of events reported. The data must be analyzed and appropriate actions taken to correct program weaknesses. The data and analysis must be retained for 3 years. Any licensee choosing to temporarily suspend individuals under the provisions of § 26.24(d) shall report test results by process stage (i.e., onsite screening, laboratory screening, confirmatory tests, and MRO determinations) and the number of temporary suspensions or other administrative actions taken against individuals based on onsite presumptive positive screening test results for marijuana (THC) and for cocaine.

§ 26.73 Reporting requirements.

(a) Each licensee subject to this part shall inform the Commission of significant FFD events including, but not limited to:

(1) Sale, distribution, use, possession, or presence of illegal drugs or use or presence of alcohol within the protected area;

(2) Any acts by any person licensed under 10 CFR part 55 to operate a power reactor, by any supervisory personnel assigned to perform duties within the scope of this part, or by any FFD program personnel as specified in § 26.2(a)(4)--

(i) Involving the sale, use, or possession of a controlled substance;

(ii) Resulting in determinations that such an individual has violated the licensee's FFD policy including subversion as defined in § 26.3;

(iii) Involving use of alcohol within the protected area; or

(iv) Resulting in a determination of unfitness for scheduled work due to the consumption of alcohol.

(3) Any act that would cast doubt on the integrity of the FFD program, including, but not limited to, acts that cast doubt on the honesty and integrity of the FFD program personnel specified in § 26.2(a)(4),

(4) Arrest of a worker for sale, distribution, use, or possession of illegal drugs on or off site.

(b) Notification must be made to the NRC Operations Center by telephone within 24 hours of the discovery of the event by the licensee.

(c) Fitness-for-duty events must be reported under this section rather than reported under the provisions of § 73.71.

(d) By November 30, 1993, each licensee that is authorized to possess, use, or transport formula quantities of SSNM shall certify to the NRC that it has implemented a fitness-for-duty program that meets the requirements of 10 CFR part 26. The certification must describe any licensee cut-off levels more stringent than those imposed by this part.

AUDITS

§ 26.80 Audits.

(a) Each licensee subject to this part shall completely audit the FFD program as needed but no less frequently than every 36 months. Licensees are responsible for determining the appropriate frequency, scope, and depth of additional auditing activities within the 3-year period based on review of program performance indicators such as the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes,

previous audit findings, and "lessons learned." As soon as reasonably practicable, but not later than 12 months after a significant change in FFD personnel, procedures, or equipment, licensees shall audit the particular program element(s) affected by that change to assure continued program effectiveness. Program elements that must continue to be audited nominally every 12 months include FFD program elements implemented by contractors and vendors under the provisions of § 26.23, testing performed at HHS-certified laboratories, and FFD services provided to the licensee by personnel who are off site or not under the direct daily supervision or observation of licensee personnel. Licensees may accept audits of contractors and vendors conducted by other licensees and need not re-audit the same contractor or vendor for the same period of time. Each sharing utility shall maintain a copy of the audit report, to include findings, recommendations and corrective actions. Licensees retain responsibility for the effectiveness of contractor and vendor programs and the implementation of appropriate corrective action.

(b) Audits must focus on the effectiveness of the program and be conducted by individuals qualified in the subject(s) being audited, and independent of both FFD program management and personnel directly responsible for implementation of the FFD program.

(c) The result of the audit, along with recommendations, if any, must be documented and reported to senior corporate and site management. The audit report must identify conditions adverse to the proper performance of the FFD program, the cause of the condition(s) and, when appropriate, recommend corrective actions. Management shall review the audit findings and take follow-up action, including re-audit of the deficient areas where indicated, to preclude, within reason, repetition of the condition. The resolution of the audit findings and corrective actions must be documented. These documents must be retained for 3 years.

ENFORCEMENT

§ 26.90 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of--

- (1) The Atomic Energy Act of 1954, as amended;
- (2) Title II of the Energy Reorganization Act of 1974; or
- (3) Any regulation or order issued under these Acts.

(b) A court order may be obtained for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act of 1954, for violations of--

- (1) Section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act;
- (2) Section 206 of the Energy Reorganization Act of 1974;
- (3) Any rule, regulation, or order issued under these Sections;

(4) Any term, condition, or limitation of any license issued under these Sections; or
(5) Any provisions for which a license may be revoked under section 186 of the Atomic Energy Act of 1954.

§ 26.91 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the

regulations in part 26 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 26 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 26.1, 26.2, 26.3, 26.4, 26.6, 26.7, 26.8, 26.90, and 26.91.

APPENDIX A TO PART 26--GUIDELINES FOR DRUG AND ALCOHOL TESTING PROGRAMS

Subpart A--General

- 1.1 Applicability.
- 1.2 Definitions.
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Subpart C--Employee Protection

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Subpart D--Certification of Laboratories Engaged in Chemical Testing

- 4.1 Use of HHS-Certified Laboratories

Subpart A--General

- 1.1 Applicability.

(a) These guidelines apply to licensees authorized to operate nuclear power reactors and licensees that are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM).

(b) Licensees may set more stringent cut-off levels than specified herein or test for substances other than specified herein and shall inform the Commission of the deviation within 60 days of implementing such change. Licensees may not deviate from the other provisions of these guidelines without the written approval of the Commission.

(c) Only laboratories which are HHS-certified are authorized to perform urine drug testing for NRC licensees, vendors, and licensee contractors.

- 1.2 Definitions.

In addition to the definitions contained in § 26.3, the following definitions apply:

Chain of custody. Procedures to account for the integrity of each specimen by tracking its handling and storage from the point of specimen collection to final disposition of the specimen.

Collection site. A place designated by the licensee where individuals present themselves for the purpose of providing a specimen of their urine, breath, and/or blood to be analyzed for the presence of drugs or alcohol.

Collection site person. A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the specimen(s) provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein. In any case where: a collection is observed or collection is monitored by non-medical personnel, the collection site person must be a person of the same gender as the donor.

Limit of detection (LOD). The lowest concentration of an analyte that an analytical procedure can reliably detect, which should be significantly lower than the established cut-off levels.

1.3 Future Revisions

In order to adapt the rule to changes in the evolving disciplines related to substance abuse and employee fitness and ensure the full reliability and accuracy of drug assays, the accurate reporting of test results, and the integrity and efficiency of drug testing programs conducted under the provisions of 10 CFR Part 26, the Commission may make changes to these Guidelines to reflect improvements in the available science and technology, in response to additional experience, or as other considerations warrant.

Subpart B--Scientific and Technical Requirements

2.1 The Substances.

(a) Licensees shall, at a minimum, test for marijuana, cocaine, opiates, amphetamines, phencyclidine, and alcohol for pre-access, for-cause, random, follow-up, and return-to-duty tests.

(b) Licensees may test for any illegal drugs or any other substances suspected of having been abused and may consider any detected drugs or metabolites when determining appropriate action during a for-cause test, a return-to-duty test after removal from access under § 26.27(b) or (c), any test of an individual who is in a follow-up testing program, or analysis of any specimen suspected of being adulterated or diluted (in vivo or in vitro), substituted, or tampered with by any other means.

(c) Licensees shall establish rigorous testing procedures that are consistent with the intent of these guidelines for any other drugs not specified in these guidelines for which testing is authorized under 10 CFR Part 26, so that the appropriateness of the use of these substances can be evaluated by the Medical Review Officer (MRO) to ensure that individuals granted unescorted access are fit for maintaining access to and for performing duties in protected areas.

(d) Specimens collected under NRC regulations requiring compliance with this part may only be designated or approved for testing as described in this part and shall not be used to conduct any other analysis or test without the permission of the tested individual.

(e) This section does not prohibit procedures reasonably incident to analysis of a specimen for controlled substances (e.g., determination of pH or tests for specific gravity, creatinine concentration, or presence of adulterants).

2.2 General Administration of Testing.

The licensee testing facilities and HHS-certified laboratories described in this part shall develop and maintain clear and well-documented procedures for collection, shipment, and accession of urine and blood specimens under this part. These procedures must include, as a minimum, the following:

(a) Use of a custody-and-control form. The original must accompany the specimen to the HHS-certified laboratory. A copy must accompany any split specimen. The form must be a record on which is retained identity data (or codes) on the individual providing the specimen and information on the specimen collection process and transfers of custody of the specimen. Custody-and-control forms related to determinations of violations of the fitness-for-duty (FFD) policy must be retained as required by § 26.71(b) and (c), or until the completion of all legal proceedings related to the violation, whichever is later. Custody-and-control forms recording specimens with negative test results and no FFD violations or anomalies may be destroyed after appropriate summary information has been recorded for program administration purposes.

(b) Use of a tamper-evident sealing system designed in a manner such that the specimen container top can be sealed against undetected opening, the container can be identified with a unique identifying number identical to that appearing on the custody-and-control form, and space has been provided to initial the container affirming its identity. For purposes of clarity, this requirement assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which one or more specimens and associated paperwork may be transferred and which can be sealed and initialed to prevent undetected tampering.

(d) Written procedures, instructions, and training must be provided as follows:

(1) Licensee collection site procedures and training of collection site personnel shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the individual tested, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A non-medical collection site person shall receive training in compliance with this appendix and shall demonstrate proficiency in the application of this appendix before serving as a collection site person. A medical professional, technologist, or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided the instructions described in § 2.2(d)(3) of this appendix and performs collections in accordance with those instructions.

(3) Collection site persons shall be provided with detailed, clearly-illustrated, written instructions on the collection of specimens in compliance with this part. Individuals subject to testing shall also be provided standard written instructions setting forth their responsibilities.

(4) The option to provide a blood specimen for the purposes of obtaining additional information that could be considered during an appeal pursuant to § 26.28 following a positive confirmatory breath test must be specified in the written instructions provided to individuals tested.

2.3 Preventing Subversion of Testing.

Licensees shall carefully select and monitor persons responsible for administering the testing program (e.g., collection site persons, onsite testing facility technicians, MROs, and those selecting and notifying personnel to be tested), based upon the highest standards for honesty and integrity, and shall implement measures to ensure that these standards are maintained. At a minimum, these measures must ensure that the integrity of such persons is not compromised or subject to efforts to compromise due to personal relationships with any individuals subject to testing.

At a minimum:

(a) Supervisors, co-workers, and relatives of the individual being tested shall not perform any collection, assessment, or evaluation procedures.

(b) FFD program personnel shall be tested by personnel independent of the administration of the FFD program to the extent practicable.

(c) Appropriate background checks and psychological evaluations of the FFD program personnel specified in § 26.2(a) must be completed before assignment of tasks directly associated with the licensee's administration of the program, and must be conducted at least once every 5 years.

(d) Persons, specified in § 26.2(a), responsible for administering the testing program shall be subjected to a behavioral observation program designed to assure that they continue to meet the highest standards for honesty and integrity.

2.4 Specimen Collection Procedures.

(a) Designation of Collection Site. Each drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine or blood specimens to a drug testing laboratory. A properly equipped mobile facility that meets the requirements of this part is an acceptable collection site.

(b) Collection Site Person. A collection site person shall have successfully completed training to carry out this function. In any case where the collection of urine is observed, the collection site person must be a person of the same gender as the donor. Persons drawing blood shall be qualified to perform that task.

(c) Security. Measures shall be provided to prevent unauthorized access which could compromise the integrity of the collection process or the specimen. Security procedures shall provide for the designated collection site to be secure. If a collection site facility cannot be dedicated solely to drug and alcohol testing, the portion of the facility used for testing shall be secured during that testing.

(1) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present, and that undetected access (e.g., through a rear door not in the view of the collection site person) is impossible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the individual or distraction of the collection site person.

(2) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed container is transferred for shipment, the

following minimum procedures shall apply: The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in a mailer or secured for shipment. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under the personal control of the collection site person. These minimum procedures shall apply to the mailing of specimens to licensee testing facilities from collection sites (except where co-located) as well as to the mailing of specimens to HHS-certified laboratories. As an option, licensees may ship several specimens via courier in a locked or sealed shipping container.

(d) Chain-of-Custody. Licensee custody-and-control forms must be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine and blood specimens from one authorized individual or place to another must always be accomplished through chain-of-custody procedures. Since chain-of-custody documentation for each urine specimen must be attached to the specimen bottle and the specimen bottles must be placed in a sealed, tamper-evident shipping container for shipment to the drug testing laboratory, both as required by § 2.4(i), couriers, express carriers, and postal service personnel do not have access to the custody-and-control forms. Therefore, there is no requirement that such personnel document chain of custody on the custody-and-control forms during transit. Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service. Every effort must be made to minimize the number of persons handling the specimens.

(e) Access to Authorized Personnel Only. No unauthorized personnel shall be permitted in any part of the designated collection site where specimens are collected or stored. Only the collection site person may handle specimens before their securement in the mailing or shipping container or monitor or observe specimen collection (under the conditions specified in this part). To promote security of specimens, avoid distraction of the collection site person, and ensure against any confusion in the identification of specimens, a collection site person shall conduct only one collection procedure at any given time. For this purpose, a collection procedure is complete when the specimen container has been sealed and initialed, the custody-and-control form has been executed, and the individual has departed the collection site.

(f) Privacy. Procedures for collecting urine specimens must allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided. For purposes of this appendix, the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute a urine specimen:

(1) The individual has presented, at this or any previous collection, a urine specimen that failed to meet the standards for an acceptable specimen as described in § 2.4(g) (15) of this appendix, or the specimen was determined to be of questionable validity or invalid under the provisions of § 2.7(e) of this appendix unless it was determined by MRO review, after special processing of the specimen as provided in that section, that no violation of the licensee's FFD policy occurred.

(2) The individual has presented a urine specimen that falls outside the normal temperature range; and

(i) the individual declines to provide a measurement of oral body temperature by sterile thermometer, as provided in § 2.4(g)(15) of this appendix; or

(ii) the individual's oral temperature varies by more than 1°C/1.8°F from the temperature of the specimen.

(3) The last urine specimen provided by the individual (i.e., on a previous occasion) was determined to have a specific gravity of less than 1.003 or a creatinine concentration below 20

milligrams per deciliter unless it was determined by MRO review after special processing of the specimen as provided in § 2.7(e) of this appendix that no violation of the licensee's FFD policy occurred.

(4) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the specimen.

(5) The individual has previously been determined to have used a substance inappropriately or without medical authorization and the particular test is being conducted as a part of a rehabilitation program or on return to service after evaluation and/or treatment for a confirmed positive test result.

(g) Integrity and Identity of Specimens. Licensees shall take precautions to ensure that a urine specimen is not adulterated, diluted, or tampered with during the collection procedure, that a surrogate specimen is not provided, that a blood specimen or breath exhalent tube cannot be substituted or tampered with, and that the information on the specimen container and on the custody-and-control form can identify the individual from whom the specimen was collected. The following minimum precautions must be taken to ensure that authentic specimens are obtained and correctly identified:

(1) To deter the dilution of urine specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure, it shall be effectively secured or monitored to ensure it is not used (undetected) as a source for diluting the specimen.

(2) When an individual arrives at the collection site for a urine or breath test, the collection site person shall ensure that the individual is positively identified as the person selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive for a urine or breath test at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) After the individual has been positively identified, the collection site person shall ask the individual to sign a consent-to-testing form. The individual shall not be required to list prescription medications or over-the-counter preparations that he or she can remember using.

(5) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room in which the urine specimen is collected. The individual may retain his or her wallet.

(6) The individual shall be instructed to wash and dry his or her hands prior to urination.

(7) After washing hands prior to urination, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the urine specimen.

(8) The individual may provide his or her urine specimen in the privacy of a stall or otherwise partitioned areas that allows for individual privacy.

(9) The collection site person shall note any unusual behavior or appearance on the custody-and-control form.

(10) In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement for urine specimen collection (e.g., an accident investigation), a public or onsite rest room may be used according to the following procedures. A collection site person of the same gender as the individual shall accompany the individual into the rest room which shall be made secure during the collection procedure. If practicable, a toilet bluing agent must be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain-of-custody procedures. If a collection site person of the same gender is not available, the licensee shall select a same gender person to accompany the individual. This person shall be briefed on relevant collection procedures.

(11) Upon receiving a urine specimen from the individual, the collection site person shall determine whether it contains a quantity of urine sufficient to meet specific licensee testing program requirements. This quantity must be predetermined by each licensee and must take into account all analyses and reanalyses provided for in the licensee's FFD policy. The predetermined quantity for any particular specimen must include at least 30 milliliters for the testing at the HHS-certified laboratory required under § 2.1(a) of this appendix plus an appropriate additional quantity if the licensee tests for additional drugs. Where collected specimens are to be split under the provisions of § 2.7(k) of this appendix, the predetermined quantity must include at least an additional 15 milliliters. The predetermined quantity should also provide for an additional quantity for onsite testing, if the licensee conducts such testing. In cases where the specimen volume is insufficient to fulfill all analysis and reanalysis requirements as predetermined by the licensee, the specimen should be used to the extent possible to meet those requirements in the following order of priority: testing of the specimen at the HHS-certified laboratory, provision for a split specimen, and onsite screening tests. Partial specimens (less than 30 milliliters) should be retained and sent with any subsequently collected specimen(s) for testing at the HHS-certified laboratory. If there is less than the quantity of urine in the container required for HHS-certified laboratory testing, additional urine must be collected. Each successive void must be collected in a separate container. (The temperature of any specimen in its separate container must be measured in accordance with § 2.4 (g)(13) of this appendix, and the specimen must be inspected, sealed, and labeled as described below for a specimen that meets the licensee's full volume requirements.) Each specimen must be sent separately for analysis. The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., normally, an 8 oz. glass of water every 30 minutes, but not to exceed a maximum of 24 oz.). If the individual fails for any reason to provide a quantity of urine sufficient to fulfill all analysis and reanalysis requirements as predetermined by the licensee, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(12) After the urine specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(13) Immediately after the urine specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement must in no case exceed 4 minutes, and may need to be less because of the ambient temperature.

(14) If the temperature of a urine specimen is outside the range of 32.5°-37.7 °C/90.5°-99.8°F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person. Both specimens shall be forwarded to the laboratory for testing. Immediately after a urine specimen is collected, the collection site person shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. Any unusual findings must be noted on the custody-and-control form.

(15) A specimen acceptable for further processing is free of any contaminants, meets the required quantity of at least 30 ml, and is within the acceptable temperature range.

(i) An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(ii) If there is a reason to believe that the individual may have altered or substituted the specimen because one or more of the acceptance criteria is not met or there is other reason to believe that the individual is attempting to subvert the testing process, another specimen must be collected immediately under direct observation of a same gender collection site person. If a collection site person of the same gender is not available, the licensee shall select a same gender observer. The observer shall be briefed on relevant collection procedures. The same measurements must be performed on the second specimen, and both specimens must be forwarded to the laboratory for testing.

(16) All urine specimens suspected of being adulterated or found to be diluted shall be forwarded to the laboratory for testing.

(17) Whenever there is reason to believe that a particular individual may have altered or substituted a specimen or may alter or substitute the urine specimen to be provided, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person. Where appropriate, measures will be taken to prevent additional hydration.

(18) Alcohol breath tests must be performed by using evidential-grade equipment as specified in § 2.7(p)(3) of this appendix. The equipment must be operated in accordance with the manufacturer's instructions by individuals trained and proficient in the use of the equipment. If there is reason to believe a source of alcohol in the mouth exists (e.g., breath freshener or stomach contents) and the testing device does not have built-in protection for the condition, the collection of the first screening breath specimen must be delayed 15 minutes to allow for dissipation of the material. If the analysis of the first screening breath specimen is essentially zero (less than 0.01 percent blood alcohol concentration [BAC]), the test is considered negative and no further testing is required. For each individual whose first screening breath specimen is at or above 0.01 percent BAC, a second screening breath specimen is to be collected and compared on the same equipment as the first screening breath specimen after 2 minutes but no later than 10 minutes after the first specimen is collected. If the two specimens are within plus or minus 10 percent of the average of the two measurements, then the screening test result is considered accurate. If the screening test result is not accurate, the series of two screening breath tests must be repeated on another evidential-grade breath analysis device ensuring that the plus or minus 10 percent accuracy is achieved. If the result of the screening test is greater or equal to 0.02 percent BAC, a confirmatory test must be accomplished. The confirmatory test is a repeat of the screening test procedure done on another evidential-grade breath analysis device.

(19) If the alcohol breath tests indicate that the individual is positive for a BAC at or above the 0.04 percent cut-off level or that the individual may have been positive for a BAC at

or above the 0.04 percent cut-off level during any scheduled working tour (i.e., has a confirmatory test result between 0.02 percent BAC and 0.04 percent BAC), the individual may request a blood test, at his or her discretion, for the purpose of obtaining additional information that could be considered during an appeal. The blood specimen should be drawn immediately, if possible. All vacuum tube and needle assemblies used for blood collection must be factory-sterilized. The collection site person shall ensure that they remain properly sealed until use. Antiseptic swabbing of the skin must be performed with a nonethanol antiseptic. Sterile procedures must be followed when drawing blood and transferring the blood to a storage container; in addition, the container must be sterile and sealed.

(20) Both the individual being tested and the collection site person shall keep urine and blood specimens in view at all times before their being sealed and labeled. If a urine specimen is split (as described in § 2.7(k)) and if any specimen is transferred to a second container, the collection site person shall request the individual to observe the splitting of the urine specimen or the transfer of the specimen and the placement of the tamper-evident seal over the container caps and down the sides of the containers.

(21) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (h) through (j) of this section.

(22) The collection site person shall place securely on each container an identification label which contains the date, the individual's specimen number, and any other identification information provided or required by the drug testing program. If separate from the labels, the tamper-evident seals shall also be applied.

(23) The individual shall initial the identification labels on the specimen bottles for the purpose of certifying that it is the specimen collected from him or her. The specimen bottles must be securely sealed to prevent undetected tampering. The individual must also be asked to read and sign a statement on the custody-and-control form certifying that the specimens identified as having been collected from him or her are, in fact, the specimens that he or she provided.

(24) Agreement of the MRO, other designated medical professional, or a higher level supervisor of the collection site person, must be obtained in advance of each decision to obtain a urine specimen under direct observation as specified in § 2.4(g)(15).

(25) The collection site person shall complete the custody-and-control forms for both the primary specimen and the split specimen, if collected, and shall certify proper completion of the collection.

(26) The specimens and custody-and-control forms are now ready to be packaged for transfer to the laboratory or the licensee's testing facility. If the specimens are not immediately prepared for shipment, they shall be appropriately safeguarded during temporary storage.

(27) While any part of the above chain-of-custody procedures is being performed, it is essential that the specimens and custody documents be under the control of the involved collection site person. The collection site person must not leave the collection site in the interval between presentation of the specimen by the individual and securement of the specimens with identifying labels bearing the individual's specimen identification numbers and seals initialed by the individual. If the involved collection site person leaves his or her work station momentarily, the sealed specimens and custody-and-control forms must be taken with him or her or must be secured. If the collection site person is leaving for an extended period of time, the specimens must be packaged for transfer to the laboratory before he or she leaves the collection site.

(h) Collection Control. To the maximum extent possible, collection site personnel must keep the individual's specimen containers within sight both before and after the individual has

urinated or provided a blood specimen. After the specimen is collected and whenever urine specimens are split, they must be properly sealed and labeled to prevent undetected tampering. The collection site person shall sign or initial and date the specimen seal. A custody-and-control form must be used for maintaining control and accountability of each specimen including split specimens from the point of collection to final disposition of the specimen. The date and purpose must be documented on the custody-and-control form each time a specimen is handled or transferred, and every individual in the chain of custody must be identified. Every effort must be made to minimize the number of persons handling specimens.

(i) Specimen Preparation for Transportation to Laboratory or Testing Facility. Collection site personnel shall arrange to transfer the collected specimens to the drug testing laboratory or licensee testing facility. Licensees shall take appropriate and prudent actions to minimize false negative results from specimen degradation. At a minimum, collected urine specimens must be shipped to the HHS-certified laboratory, or cooled to not more than 6 degrees centigrade (42.8°F), within 6 hours of collection. Specimens must be sent to the HHS-certified laboratory as soon as reasonably possible but, except under unusual circumstances, the time between specimen shipment and receipt of the specimen at the HHS-certified laboratory should not exceed 48 hours, or the time between shipment and the screening test at the HHS-certified laboratory exceed 72 hours. The collection site personnel shall ensure that the custody-and-control form is packaged with its associated urine specimen bottle. Sealed and labeled specimen bottles, with their associated custody-and-control forms, being transferred from the collection site to the drug testing laboratory must be placed in a second, tamper-evident shipping container which must be designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal.

(j) Failure to Cooperate. If the individual attempts to subvert the testing process or otherwise refuses to cooperate with the urine collection or breath analysis process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen; provides incorrect or incomplete personal information), then the collection site person shall inform the appropriate authority and shall document the non-cooperation on the specimen custody-and-control form. The failure to cooperate must be reported immediately to the MRO, the FFD Program Manager, or to other management having a need to know, as appropriate, for further action. The provision of a blood specimen for use in an appeal of a positive breath test for alcohol must be entirely voluntary, and must be at the individual's option.

2.5 HHS-Certified Laboratory Personnel.

(a) Day-to-Day Management of the HHS-certified Laboratories.

(1) The HHS-certified laboratory shall have a responsible person to assume professional, organizational, educational, and administrative responsibility for the laboratory's drug testing facilities.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the appropriate State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology (e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology).

(3) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual must be reviewed, signed, and dated by this responsible person whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect must be maintained. (Specific contents of the procedure manual are described in § 2.7(p) of this appendix.)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that test results are not reported until all corrective actions have been taken and he or she can assure that the test results provided are accurate and reliable.

(b) Test Validation. The laboratory's urine drug testing facility shall have a certifying scientist(s) as defined in section 1.2 of the HHS Guidelines, June 9, 1994; 59 FR 29908 who reviews all pertinent data and quality control results to attest to the validity of the laboratory's test reports. A laboratory may designate certifying scientists who are qualified to certify only results that are negative on the initial test and certifying scientists who are qualified to certify both initial and confirmatory tests.

(c) Day-to-Day Operations and Supervision of Analysts. The laboratory's urine drug testing facility shall have an individual(s) to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the

review, interpretation, and reporting of test results; maintenance of chain-of-custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) Other Personnel. Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) Training. The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) Files. Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

2.6 Licensee Testing Facility Personnel.

(a) Day-to-Day Management of Operations. Any licensee testing facility shall have an individual to be responsible for day-to-day operations and to supervise the testing technicians. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the licensee testing facility, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; and proper remedial actions to be taken in response to detecting aberrant test or quality control results.

(b) Other Personnel. Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(c) Files. Licensees' testing facility personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate; and appropriate data to support determinations of honesty and integrity conducted in accordance with § 2.3 of this appendix.

2.7 Laboratory and Testing Facility Analysis Procedures.

(a) Security and Chain of Custody.

(1) HHS-certified drug testing laboratories and any licensee testing facility shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records and split specimens are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times in the HHS-certified laboratory and in the licensee's testing facility. Documentation of individuals accessing these areas, dates, and times of entry and purpose of entry must be maintained.

(2) Laboratories and testing facilities shall use chain-of-custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate custody-and-control form each time a specimen is handled or transferred, and every individual in the chain shall be identified.

Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete custody-and-control forms for those specimens or aliquots as they are received.

(b) Receiving.

(1) When a shipment of specimens is received, laboratory and the licensee's testing facility personnel shall inspect each package for evidence of possible tampering and compare information on specimen containers within each package to the information on the accompanying custody-and-control forms. Any direct evidence of tampering or discrepancies in the information on specimen containers and the licensee's custody-and-control forms attached to the shipment must be reported by the HHS-certified laboratory within 24 hours to the licensee in the case of HHS-certified laboratories and must be noted on the laboratory's custody-and-control form which must accompany the specimens while they are in the laboratory's possession. Indications of tampering with specimens at a testing facility operated by a licensee must be reported within 8 hours to senior licensee management.

(2) Specimen containers will normally be retained within the laboratory's or testing facility's accession area until all analyses have been completed. Aliquots and the custody-and-control forms shall be used by laboratory or testing facility personnel for conducting screening and confirmatory tests, as appropriate.

(c) Short-Term Refrigerated Storage. Specimens that do not receive a screening test and, if appropriate, a confirmatory test within 1 day of arrival at the HHS-certified laboratory, or are not shipped within 6 hours of collection from the licensee's collection or testing facility as well as any retained split specimens must be placed in secure refrigeration units or other means of securely maintaining the specimens in a chilled condition until testing or shipment. Temperatures must not exceed 6°C/43°F. Contingency measures must be available to maintain the specimens in a chilled state in case of prolonged power failure.

(d) Specimen Processing. Urine specimens identified as presumptively positive or as questionable for adulteration or dilution by a licensee's testing facility must be shipped to an HHS-certified laboratory for testing. Laboratory facilities for drug testing will normally process urine specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either screening or confirmatory tests at either the licensee's testing facility or an HHS-certified laboratory, every batch must contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test specimens must appear as ordinary specimens to laboratory analysts. Special processing may be conducted to analyze specimens suspected of being adulterated or diluted (including hydration). Any evidence of adulteration or dilution, and any detected trace amounts of drugs or metabolites, must be reported to the MRO. The MRO shall report any adulteration or dilution evidence (excluding hydration resulting from an acceptable reason) to management immediately.

(e) Determining Specimen Validity.

(1) Licensees should take prudent and appropriate actions to assure specimen validity. Devices used to determine validity of the specimen on site and at HHS-certified laboratories must be accurate and not contaminate the specimen. At a minimum, the following actions must be taken. Equivalent processes may be used when acceptable to the HHS laboratory certification program; additional measures may be taken as changes to subversion technology take place. Specimens that are to be tested at the licensee's testing facility must first be tested for creatinine, specific gravity, pH, and nitrites. If a specimen's creatinine concentration is less than 20 milligrams per deciliter, if the specific gravity is less than 1.003, if the pH is less than

4.8 or greater than 7.8, if the nitrite concentration is equal to or greater than 500 micrograms per milliliter, or if there is other evidence of adulterants, the specimen must be sent to the HHS-certified laboratory for processing. HHS-certified laboratories must test these specimens and all other urine specimens forwarded under the provisions of § 26.24(d)(1) to determine their validity and to detect evidence of adulteration or dilution. At a minimum, such testing must include analysis for creatinine, pH, and nitrites (and specific gravity when acquisition and certification of automated methods are completed) before being subjected to screening testing. If a specimen's creatinine concentration is less than 20 milligrams per deciliter, the laboratory must measure the specimen's specific gravity.

(2) A valid specimen acceptable for testing using the cut-off levels in §§ 2.7(f)(1) and 2.7(g)(2) of this appendix, at either a licensee's testing facility or an HHS-certified laboratory, is free of adulterants and has a creatinine level equal to or greater than 20 milligrams per deciliter, a pH concentration between 4.8 and 7.8 (inclusive), a nitrite concentration less than 500 micrograms per milliliter, and a specific gravity equal to or greater than 1.003 (when applicable). Specimens not meeting these standards are to be considered either adulterated, diluted, or of questionable validity.

(3) A specimen is invalid if it is either diluted or adulterated. A specimen is invalid if it has a creatinine concentration equal to or less than 7 milligrams per deciliter in combination with a specific gravity measurement equal to or less than 1.001 or in combination with a specific gravity measurement equal to or greater than 1.020, a pH measurement equal to or less than 3.5 or equal to or greater than 11.0, a nitrite concentration equal to or greater than 500 micrograms per milliliter, or if it has detectable adulterants. When a laboratory determines that a specimen is invalid, it need not conduct further testing but must report the possibly diluted or adulterated condition and the quantitated results of all testing to the MRO.

(4) A specimen of questionable validity is a specimen that contains no detectable adulterants but shows evidence of dilution by having a combined creatinine/specific gravity result that falls between a creatinine concentration greater than 7 milligrams per deciliter in combination with a specific gravity greater than 1.001 and a creatinine concentration of less than 20 milligrams per deciliter in combination with a specific gravity of less than 1.003, or by having a pH concentration greater than 3.5 but less than 4.8 or greater than 7.8 but less than 11.0. Specimens determined to be of questionable validity must be subject to screening testing using FDA-approved analytical kits having the lowest concentration levels marketed for the screening technology(ies) being used. The responses of questionable donor specimens must be compared to the acceptable range of negative screening control responses. Those specimens that have responses that are greater than the negative control responses must be subject to confirmation testing by GC/MS at the laboratory's limit of detection (LOD). Such testing need be conducted only for the substance(s) responded to in the screening test. Quantified test results must be reported to the MRO. Negative screening results for this special processing must be reviewed by the MRO, and, if the MRO has reason to believe that the dilution is the result of a subversion attempt, the specimen must also be subject to GC/MS testing at the laboratory's LOD.

(5) When the MRO cannot determine if the specimen is valid or invalid, another specimen must be collected as soon as possible under the direct observation of a same gender collection site person.

(f) On-site and Laboratory Screening Tests.

(1) For the analysis of urine specimens, any screening test performed by a licensee's testing facility and the screening test performed by an HHS-certified laboratory must use an immunoassay which meets the requirements of the Food and Drug Administration for

commercial distribution. Pending HHS (SAMSHA) review and approval of non-instrumented immunoassay testing devices, such devices shall not be used to test for drugs of abuse in NRC-regulated FFD programs. Non-instrumented devices may be used for the tests to determine specimen validity required by § 2.7(e). The screening test of breath for alcohol performed at the collection site must use a breath measurement device which meets the requirements of § 2.7(p)(3). The following cut-off levels must be used when screening specimens to determine whether they are negative for the indicated substances:

Screening test cut-off level (ng/ml)

Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites ¹	300
Phencyclidine	25
Amphetamines	1,000
Alcohol ²	0.04% BAC

¹25 ng/ml is immunoassay specific for free morphine.

²Percent, by weight, of alcohol in a person's blood shall be based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath.

In addition, licensees may specify more stringent cut-off levels. In these cases, the results of HHS screening tests must be reported for both levels. Only the more stringent tests need be conducted, and the results for the cut-off levels above may be calculated.

(2) The list of substances to be tested and the cut-off levels, along with the procedures, quality controls, and standards applicable to specimen collection, analysis, and validity, are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant such changes.

(3) Multiple screening tests (also known as rescreening) for the same drug class may be performed only on:

(i) presumptively positive specimens (e.g., a presumptive positive screening test result for amphetamines) only when needed to reduce the effect of possible cross reactivity due to structural analogs;

(ii) those specimens where a valid analytical result cannot be obtained using one particular immunoassay technique due to interference in the assay (e.g., prescription medication); or

(iii) presumptively positive specimens that appear to have a high concentration of drugs or metabolites to determine an appropriate dilution requirement for GC/MS confirmation analysis.

(g) Confirmatory Test.

(1) Specimens which test negative as a result of the HHS-certified laboratory screening test must be reported as negative to the licensee and will not be subject to any further testing unless special processing of the specimen is desired because adulteration or dilution is suspected.

(2) Except as required by § 2.7(e), all specimens identified as presumptively positive on the screening test performed by an HHS-certified laboratory must be confirmed using GC/MS techniques at the cut-off values listed in this paragraph for each drug, or at the cut-off values required by the licensee's unique program, where differences exist. All confirmations must be made by quantitative analysis. Concentrations which exceed the linear region of the standard curve must be documented in the laboratory record as "greater than highest standard curve value."

Confirmatory test cut-off level (ng/ml)	
Marijuana metabolite ¹	15
Cocaine metabolite ²	150
Opiates:	
Morphine	300
Codeine	300
6-Acetylmorphine ³	10
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine ⁴	500
Alcohol ⁵	0.04% BAC

¹Delta-9-tetrahydrocannabinol-9-carboxylic acid.

²Benzoyllecgonine.

³Test for 6-AM when the confirmatory test shows a morphine concentration exceeding 2,000 ng/ml.

⁴Specimen must also contain amphetamine at a concentration \geq 200 ng/ml.

⁵Percent, by weight, of alcohol in a person's blood shall be based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath.

In addition, licensees may specify more stringent cut-off levels. In these cases, the results must be reported for both levels. Only the more stringent tests need be conducted, and the results for the cut-off levels above may be calculated.

(3) The analytic procedure for analysis of blood specimens voluntarily provided by individuals testing positive for alcohol on a breath test must be gas chromatography analysis.

(4) The list of substances to be tested and the cut-off levels, along with the procedures, quality controls, and standards applicable to specimen collection, analysis, and validity, are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant such changes.

(5) Specimens that have a positive GC/MS test result for amphetamines must be tested for the *d* and *l* isomers. The results of this additional test must be reported to the MRO. Laboratory quality control and inspection criteria must be included for this additional test.

(h) Reporting Results.

(1) The HHS-certified laboratory shall report test results to the licensee's MRO within 5 working days (6 for suspected amphetamines) after receipt of the specimen by the laboratory. Before any test result is reported, the results of screening tests, confirmatory tests, and quality control data, as applicable, must be reviewed and the test certified as an accurate report by the responsible individual at the laboratory. The report must identify the substances tested for, whether positive or negative; the cut-off(s) for each; the specimen number assigned by the licensee; any indications of tampering, adulteration, or dilution that may be present; and the drug testing laboratory specimen identification number.

(2) The HHS-certified laboratory and any licensee testing facility shall report as negative all specimens, except suspect specimens being analyzed under special processing, which are negative on the screening test or negative on the confirmatory test. Specimens testing positive on the confirmatory analysis must be reported positive for a specific substance. Except as provided in § 26.24(d), presumptive positive results of screening testing at the licensee's testing facility will not be reported to licensee management. The MRO's staff may perform routine administrative support functions, including receipt of test results and scheduling interviews for the MRO.

(3) The MRO may routinely obtain from the HHS-certified laboratory, and the laboratory must provide, quantitation of test results. The MRO may only disclose quantitation of test results for an individual to licensee management if required in an appeals process, or to the individual under the provisions of § 26.29(c). (This does not preclude the provision of program performance data under the provisions of § 26.71(d).) Quantitation of negative tests for urine specimens shall not be disclosed, except where deemed appropriate by the MRO for proper disposition of the results of tests of suspect specimens. Alcohol quantitation for a blood specimen must be provided to licensee management with the MRO's evaluation.

(4) The laboratory may transmit results to the MRO by various electronic means (e.g., teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone from HHS-certified laboratory personnel to the MRO. The HHS-certified laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall retain the original custody-and-control form and must send only to the MRO certified true copies of the original custody-and-control form and the test report. In the case of a laboratory-confirmed positive or special processing of suspect specimens, the document must be signed by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports. Laboratories must retain these documents consistent with the requirements contained in § 2.2(a) of this appendix.

(6) The HHS-certified laboratory and the licensee's testing facility shall provide to the licensee official responsible for coordination of the FFD program a monthly statistical summary of urinalysis and blood testing and shall not include in the summary any personal identifying information. Screening test data from the licensee's testing facility and the HHS-certified laboratory, and confirmation data from HHS-certified laboratories, must be included for test results reported within that month. Normally this summary must be forwarded from HHS-certified laboratories by registered or certified mail and from the licensee's testing facility not more than 14 calendar days after the end of the month covered by the summary. The summary must contain the following information:

(i) Screening Testing:

(A) Number of specimens received;

- (B) Number of specimens reported out; and
 - (C) Number of specimens screened positive for:
 - (1) Marijuana metabolites;
 - (2) Cocaine metabolites;
 - (3) Opiate metabolites;
 - (4) Phencyclidine;
 - (5) Amphetamines; and
 - (6) Alcohol.
 - (ii) Confirmatory Testing:
 - (A) Number of specimens received for confirmation;
 - (B) Number of specimens confirmed positive for:
 - (1) Marijuana metabolites;
 - (2) Cocaine metabolites;
 - (3) Morphine, codeine;
 - (4) Phencyclidine;
 - (5) Amphetamines;
 - (6) Methamphetamines; and
 - (7) Alcohol.
- (7) The statistics shall be presented for both the cut-off levels in these guidelines and any more stringent cut-off levels which licensees may specify. The HHS-certified laboratory and the licensee's testing facility shall make available quantitative results for all samples tested when requested by the NRC or the licensee for which the laboratory is performing drug testing services.
- (8) Unless otherwise instructed by the licensee in writing, all records pertaining to a given urine or blood specimen shall be retained by the HHS-certified drug testing laboratory and the licensee's testing facility for a minimum of 2 years.
- (i) Long-Term Storage. Long-term frozen storage (-20° C or less) ensures that any urine specimens that have been associated with personnel actions will be available for any necessary retest during administrative or disciplinary proceedings. Unless otherwise authorized in writing by the licensee, HHS-certified laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens that have been confirmed positive, or that have been adulterated or diluted. Within this 1-year period, a licensee or the NRC may request the laboratory to retain the specimen for an additional period of time. If no such request is received, the laboratory may discard the specimen after the end of 1 year. The laboratory must maintain any specimens under legal challenge for an indefinite period. Any split specimens retained by the licensee must be transferred into long-term storage upon determination by the MRO that the specimen has a laboratory confirmed positive test.
- (j) Retesting Specimens. Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite. For the retesting of specimens that have been determined to have been adulterated or diluted, the retest need only substantiate the information that the MRO used to make the initial determination.
- (k) Split Specimens. Urine specimens may be split, at the licensee's discretion, into two parts at the collection site in quantities described in § 2.4(g)(11). One part of each specimen (hereafter called the primary specimen) must be analyzed by the licensee's testing facility or the HHS-certified laboratory for the licensee's purposes as described in this appendix. The other part of the specimen (hereafter called the split specimen) may be withheld from transfer to the laboratory, sealed, and stored in a secure manner by the licensee until all processing of the

primary specimen has been completed. If the primary specimen is determined to be negative and free of any evidence of subversion, the split specimen in storage may be destroyed. If the presumptive positive screening test result of a primary specimen has been confirmed, or if the primary specimen is determined to have been subject to adulteration, dilution, or other means of testing subversion, the tested individual may request in a timely manner (as established by the licensee) that the split specimen be tested. The individual must be informed of this option, and the split specimen can be tested only at the request of the individual. The split specimen must be forwarded as soon as practicable, but in no case more than 3 week days (Monday to Friday, not including holidays) following the day of the request to another HHS-certified laboratory that did not test the primary specimen. The chain-of-custody and testing procedures to which the split specimen is subject must be the same as those used to test the primary specimen and must meet the standards for retesting specimens (i.e., the quantitation of the result is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite or substantiate the previous information ([paragraph 2.7(j)]). The quantitative results of testing of the split specimen shall be made available to the MRO and to the individual tested. Except as noted in this section, all other requirements of this appendix applicable to primary specimens shall also be applicable to split specimens. If the result of the test of the split specimen fails to reconfirm or substantiate the result reported for the primary specimen, the MRO shall take into account the primary specimen test result, the data regarding presence or absence of drug or metabolite in the split specimen, any evidence of subversion, and any other relevant information to determine whether the test results should be verified as an FFD policy violation. The licensee must investigate, take corrective action as appropriate in response to, and report to the NRC failure to reconfirm as directed in § 2.8(f) of Appendix A.

(l) Subcontracting. HHS-certified laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the licensee. The laboratory must be capable of testing the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) and of whole blood and confirmatory GC/MS methods specified in these guidelines.

(m) Laboratory Facilities.

(1) HHS-certified laboratories shall comply with applicable provisions of any State licensure requirements.

(2) HHS-certified laboratories must have the capability, at the same laboratory premises, of performing screening and confirmatory tests for each drug and drug metabolite for which service is offered and for analysis of whole blood for alcohol content (BAC). Any licensee testing facilities must have the capability, at the same premises, of performing specimen validity tests required by § 2.7(e) and screening tests for each drug and drug metabolite for which testing is conducted. Breath tests for alcohol may be performed at the collection site.

(n) Inspections and Audits. The NRC and any licensee using an HHS-certified laboratory reserve the right to inspect or audit the laboratory at any time. Licensee contracts with HHS-certified laboratories for drug testing and analyses of whole blood for alcohol content (BAC), as well as contracts for collection site services, must permit the NRC and the licensee to conduct unannounced inspections and audits and to obtain all information and documentation reasonably relevant to the inspections and audits. Licensee contracts with HHS-certified laboratories must also provide the licensee and the NRC with the ability to obtain copies of any documents, including reviews and inspections pertaining to the laboratory's certification by HHS, and any other data that may be needed to assure that the laboratory is performing its testing and quality control functions properly and that laboratory staff and procedures meet

applicable requirements. Annual licensee inspections and audits of HHS-certified laboratories need not duplicate areas inspected in the most recent HHS certification inspection, but only if the licensee reviews the HHS certification inspection records and reports to ascertain the areas covered by the HHS certification inspection. In addition, before the award of a contract, the licensee shall carry out pre-award inspections and evaluation of the procedural aspects of the laboratory's drug testing operation. If an HHS-certified laboratory loses its certification, in whole or in part, a licensee is permitted to immediately use an HHS-certified laboratory that has been audited by another NRC licensee having the same drug panel and cut-off levels. The licensee shall audit the newly contracted HHS-certified laboratory within 3 months. The NRC reserves the right to inspect a licensee's testing facility at any time.

(o) Documentation. HHS-certified laboratories and the licensee's testing facility shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by the NRC or by any licensee for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain-of-custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The HHS-certified laboratory and the licensee's testing facility shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(p) Additional Requirements for HHS-Certified Laboratories and Licensees' Testing Facilities.

(1) Procedure manual. Each laboratory and licensee's testing facility shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cut-off values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect must be maintained as part of the manual. Each HHS-certified laboratory shall retain a copy of its latest procedure manual as a record until at least 2 years after it is no longer under contract to an NRC licensee to test specimens for drugs. Each licensee that conducts onsite testing shall retain a copy of its latest procedure manual as a record until it is no longer conducting on-site testing of specimens of urine for drugs. Superseded material must be retained for at least 3 years.

(2) Standards and controls. HHS-certified laboratory standards and controls shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date. All standards and controls used to calibrate alcohol breath analysis equipment and equipment used at licensees' testing facilities for conducting screening tests must be current and valid for their purpose.

(3) Instruments and equipment.

(i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) Alcohol breath analysis equipment must be an evidential-grade breath alcohol analysis device of a brand and model that conforms to National Highway Traffic Safety

Administration (NHTSA) standards (49 FR 48855; December 14, 1984, or 58 FR 48705; September 17, 1993, or as subsequently amended) and to any applicable State statutes. Calibration units used to calibrate alcohol breath analysis equipment must be of a brand and type that conform to NHTSA standards (62 FR 43416; August 13, 1997, or as subsequently amended) and to any applicable State statutes and must be suitable for meeting the alcohol testing requirements of part 26.

(iii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. Records shall be available on preventive maintenance.

(4) Remedial actions. There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) Personnel available to testify at proceedings. The licensee's testing facility and HHS-certified laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on positive breath analysis or urinalysis results reported by the licensee's testing facility or the HHS-certified laboratory.

(6) Restrictions. The laboratory shall not enter into any relationship with a licensee's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a licensee use a specific MRO.

2.8 Quality Assurance and Quality Control.

(a) General. HHS-certified laboratories and the licensee's testing facility shall have a quality assurance program which encompasses all aspects of the testing process including, but not limited to, specimen acquisition, chain of custody, security, reporting of results, screening and confirmatory testing, and validation of analytical procedures. Quality assurance procedures must be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) Licensee's Testing Facility Quality Control Requirements for Screening Tests. Because all presumptively positive licensee facility screening tests for drugs are forwarded to an HHS-certified laboratory for screening and confirmatory testing when appropriate, the NRC does not require licensees to assess their testing facilities' false positive rates for drugs. To ensure that the rate of false negative tests is kept to the minimum that the immunoassay technology supports, licensees shall perform an immunoassay test on all blind performance test specimens and submit these and a sampling of specimens screened as negative from every test run to the HHS-certified laboratory. The results reported by the certified laboratory must be evaluated and appropriate corrective actions taken. The manufacturer-required performance tests of the breath analysis equipment used by the licensee must be conducted as set forth in the manufacturer's specifications.

(c) Laboratory Quality Control Requirements for Screening Tests at HHS-Certified Laboratories.

(1) Each analytical run of specimens to be screened must include:

- (i) Urine specimens certified to contain no drug;
- (ii) Urine specimens fortified with known standards; and

(iii) Positive controls with the drug or metabolite at or near the threshold (cut-off).

(2) In addition, with each batch of specimens, a sufficient number of standards must be included to ensure and document the linearity of the assay method over time in the concentration area of the cut-off. After acceptable values are obtained for the known standards, those values will be used to calculate specimen data. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen must be documented. A minimum of 10 percent of all test specimens must be quality control specimens. Laboratory quality control specimens, prepared from spiked urine specimens of determined concentration, must be included in the run and should appear as normal specimens to laboratory analysts. One percent of each run, with a minimum of at least one specimen, must be the laboratory's own quality control specimens.

(d) Laboratory Quality Control Requirements for Confirmation Tests. Each analytical run of specimens to be confirmed shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cut-off).

The linearity and precision of the method shall be periodically documented.

Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(e) Licensee Blind Performance Test Procedures.

(1) Licensees shall only purchase blind quality control materials that:

- (i) Have been certified by immunoassay and GC/MS; and
- (ii) Have stability data which verify performance of those materials over time.

(2) During the initial 90-day period of any contract with an HHS-certified laboratory (not including rewritten or renewed contracts), each licensee shall submit blind performance test specimens to the laboratory within the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 100 specimens) or 30 blind performance test specimens, whichever is greater. Following the initial 90-day period, a minimum of 3 percent of all specimens (to a maximum of 25) or 10 blind performance test specimens, whichever is greater, must be submitted per quarter. Licensees should make an attempt to submit blind performance test specimens during the initial 90-day period and per quarter thereafter at a frequency that corresponds with the submission frequency for other specimens.

(3) Approximately 50 percent of the blind performance test specimens must be blank (i.e., certified to contain no drug) and the remaining specimens must be positive for one or more drugs per specimen in a distribution so that all the drugs for which the licensee is testing are included in approximately equal frequencies of challenge. The positive specimens must be spiked only with those drugs for which the licensee is testing. In addition, 10 percent of the positive blind specimens must be appropriately adulterated or diluted and spiked to between 60 percent and 80 percent of the screening cut-off values established by § 2.7(f) of this appendix, or of any lower cut-off values established by the licensee, to challenge the laboratory's ability to determine specimen validity and perform special processing, as required by § 2.7(e) of this appendix.

(f) Investigation of Errors and Other Matters.

(1) The licensee shall investigate any testing errors or unsatisfactory performance discovered in blind performance testing, in the testing of actual specimens, or through the processing of appeals and MRO reviews, as well as any other errors or matters that could reflect adversely on the integrity of the testing process. The investigation must determine relevant facts and identify the root cause(s) of the testing or process error when possible. The

licensee and the laboratory shall take action to correct the cause(s) of any errors or the unsatisfactory performance that are within their control. A record must be made and retained for a minimum of 3 years of the investigative findings and the corrective action taken, and, where applicable, that record must be dated and signed by the individuals responsible for the day-to-day management and operation of the HHS-certified laboratory. The licensee shall submit to the NRC a report of any incident and action taken or planned within 30 days of completion of the investigation. The NRC shall ensure notification of the finding to HHS.

(2) Should a false positive error occur on a blind performance test specimen or on a regular specimen, the licensee shall promptly notify the NRC. The licensee shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future. If there is reason to believe the error could have been systematic, the licensee may also require review and reanalysis of previously run specimens.

(3) Should a false positive error be determined to be technical or methodological, the licensee shall instruct the laboratory to submit to it all quality control data from the batch of specimens which included any false positive specimen. In addition, the licensee shall require the laboratory to retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting must be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's substance testing program. The licensee and the NRC may require an onsite review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the NRC, HHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

2.9 Reporting and Review of Results

(a) Medical Review Officer shall review results. An essential part of a licensee's testing program is the final review of results. A laboratory confirmed positive test result does not automatically identify a nuclear power plant worker as having used substances in violation of the NRC's regulations or the licensee's company policies. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review must be performed by the MRO before the transmission of results to licensee management officials.

(b) Medical Review Officer--qualifications and responsibilities. The MRO shall be a licensed physician with knowledge of substance abuse disorders. The MRO may be a licensee or contract employee. However, the MRO shall not be an employee or agent of or have any financial interest in a laboratory or a contracted operator of an on-site testing facility whose drug testing results the MRO is reviewing for the licensee. Additionally, the MRO shall not derive any financial benefit by having the licensee use a specific drug testing laboratory or on-site testing facility operating contractor or have any agreement with such parties that may be construed as a potential conflict of interest. The role of the MRO is to review and interpret test results obtained through the licensee's testing program and to identify evidence of subversion of the testing process. The MRO is also responsible for identifying issues associated with the collection and testing of specimens, and advising and assisting management in the planning and oversight of the overall FFD program. In carrying out this responsibility, the MRO shall examine alternate medical explanations for any laboratory confirmed positive test result (this does not include confirmation of blood alcohol levels obtained through the use of a breath

alcohol analysis device). This action could include conducting a medical interview with the individual, review of the individual's medical history, or review of any other relevant biomedical factors. The MRO shall review all medical records made available by the tested individual when a laboratory confirmed positive test could have resulted from legally prescribed medication. The MRO shall not consider the results of tests that are not obtained or processed in accordance with this appendix, although he or she may consider the results of tests on split specimens in making his or her determination, as long as those split specimens have been stored and tested in accordance with the procedures described in this appendix.

(c) Medical Review Officer verification of FFD policy violations.

(1) Before making a final decision to verify a laboratory confirmed positive test result, or other occurrence that would constitute an FFD policy violation (e.g., attempted subversion), the MRO shall give the individual an opportunity to discuss the test result or other occurrence with him or her. Following verification of a laboratory confirmed positive test result or other occurrence as a violation of FFD policy, the MRO shall, as provided in the licensee's policy, immediately notify the applicable EAP and the licensee's management official empowered to recommend or take administrative action (or the official's designated agent). Presumptive positive screening test results must not be reported except as provided by § 26.24(d).

(2) The MRO may verify a laboratory confirmed positive test result, or otherwise make a determination of an FFD policy violation, without having discussed the test result or other occurrence directly with the individual in the following three circumstances:

(i) When the MRO contacts the individual, the individual expressly declines the opportunity to discuss the test result or other occurrence that may constitute an FFD policy violation;

(ii) The MRO, after making all reasonable efforts, has been unable to contact the individual within 14 days of the date on which the MRO receives notice of the laboratory confirmed positive test result, evidence of subversion of the testing process, or other activity that would constitute an FFD policy violation;

(iii) A licensee representative has successfully made and documented contact with the individual and instructed him or her to contact the MRO and more than 5 days have passed since the date the individual was successfully contacted by the licensee representative.

(3) If the MRO makes a determination of an FFD policy violation under the circumstances specified in § 2.9(c) (2) (ii) or (iii), the individual may present to the MRO information documenting that serious illness, injury, or other circumstances unavoidably prevented him or her from being contacted by the MRO or licensee representative or from contacting the MRO in a timely manner. The MRO, on the basis of this information, may reopen the procedure for determination of an FFD policy violation and allow the individual to present information relating to the issue. The MRO may modify the initial determination based on an evaluation of the information provided.

(d) Verification for opiates. Before the MRO verifies a laboratory confirmed positive result as a violation of FFD policy and the licensee takes action for opiates, he or she shall determine that there is reasonable and substantial clinical evidence--in addition to the urine test--of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). Clinical signs of abuse include recent needle tracks or test results that are inconsistent with the ingestion of food or medication including prescription medications containing opiates (e.g., 6-AM test); clinical signs of abuse also include, but are not limited to, behavioral and psychological signs of acute opiate intoxication or withdrawal, or admission of non-prescribed opiate use. This requirement does not apply if the GC/MS confirmation testing for opiates confirms the presence of 6-AM since the presence of this metabolite is proof of heroin use .

(e) Reanalysis authorized. Should any question arise as to the accuracy or validity of a laboratory confirmed positive test result, only the MRO is authorized to order a reanalysis of the original specimen and these retests are authorized only at laboratories certified by HHS. The MRO shall authorize a reanalysis of the original aliquot on timely request (as established by the licensee) by the individual tested, and shall also authorize an analysis of any split specimen stored by or for the licensee under the provisions of § 2.7(k) of this appendix.

(f) Results consistent with responsible substance use. If the MRO determines that there is a legitimate medical explanation for the laboratory confirmed positive test result, and that the use of the substance identified through testing was in the manner and at the dosage prescribed, and the results do not reflect a lack of reliability or trustworthiness, then there has not been a violation of licensee policy. The MRO shall report the test result to the licensee as negative. The MRO shall further evaluate the result and medical explanation to determine if there is a potential risk to public health and safety of the individual being impaired on duty from the substance or from the medical condition. If the MRO determines that such a risk exists, he or she shall conduct a medical determination of fitness.

(g) Medical determination of fitness.

(1) A medical determination of fitness, as defined in § 26.3, must be performed in at least the following circumstances:

(i) When an alternative medical explanation explains the test result but there is a basis for believing impairment on duty could exist, as described in § 2.9(f);

(ii) Before making return-to-duty recommendations subsequent to a worker's removal from duty in accordance with § 26.27(b) or the licensee's FFD policy;

(iii) Before an individual is granted unescorted access when information obtained pursuant to § 26.27(a) shows a history of substance abuse or record of prior FFD violations; and

(iv) If a history of substance abuse is otherwise identified.

(2) (i) If the licensed physician or MRO determines that there is neither conclusive evidence of an FFD policy violation nor a significant basis for concern that the individual may be impaired while on duty, then he or she shall report the result as negative.

(ii) If the licensed physician or MRO determines that there is not conclusive evidence of an FFD policy violation but that there is a significant basis for concern that the individual may be impaired while on duty, then he or she shall report the result as not representing an FFD policy violation but as a condition under which the individual may not be able to safely and competently perform duties. Because these results should not constitute a violation of the licensee's FFD policy or the NRC rule, punitive actions under the rule should not be taken based upon the results. However, the licensed physician, MRO, or the licensee management personnel who are empowered to take appropriate actions shall initiate actions to ensure that any possible limiting condition does not represent a threat to workplace or public health and safety. When deemed appropriate, the matter may also be referred to the EAP.

(h) Result scientifically insufficient. Additionally, the MRO, based on review of inspection reports, quality control data, multiple specimens, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation, the MRO may request reanalysis of the original specimen before making this decision. The MRO may request that reanalysis be performed by the same laboratory, or that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the HHS Guidelines. The licensee's testing facility and the HHS-certified laboratory shall assist in this review process as requested by the MRO by making available the individual(s) responsible for day-to-day management of the licensee's testing facility, of the HHS-

certified laboratory or other individuals who are forensic toxicologists or who have equivalent forensic experience in urine drug testing, to provide specific consultation as required by the licensee. The licensee shall maintain for a minimum of 3 years records that summarize any negative findings based on scientific insufficiency and shall make them available to the NRC on request, but shall not include any personal identifying information in these reports.

Subpart C--Employee Protection

3.1 Protection of Employee Records.

Licensee contracts with HHS certified laboratories and procedures for the licensee's testing facility shall require that test records be maintained in confidence, as provided in § 26.29. Records shall be maintained and used with the highest regard for individual privacy.

Subpart D--Certification of Laboratories Engaged in Chemical Testing

4.1 Use of HHS-Certified Laboratories.

(a) Licensees subject to this part and their contractors shall use only laboratories certified under the HHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs," Subpart C--"Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," (June 9, 1994, 59 FR 29908, 29925-2929) and subsequent amendments thereto for screening and confirmatory testing except for screening tests at a licensee's testing facility conducted in accordance with § 26.24(d). Information concerning the current certification status of laboratories is available from: The Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, Room 815, 5600 Fishers Lane, Rockwall 2 Bldg., Rockville, Maryland 20857.

(b) Licensees or their contractors may use only HHS-certified laboratories that agree to follow the same rigorous chemical testing, quality control, and chain-of-custody procedures when testing for more stringent cut-off levels as may be specified by licensees for the classes of drugs identified in this part, for analysis of whole blood specimens for alcohol, and for any other substances included in licensees' drug panels. Because the HHS national laboratory certification process does not cover practices outside the HHS Guidelines, such as using more stringent cutoff levels than set forth in the HHS Guidelines or testing for additional substances, licensees and their contractors that choose to use practices outside the HHS Guidelines must take measures that are consistent with this part to assure that the reported test results are valid and defensible.

(c) All contracts related to this part between licensees and their contractors and HHS-certified laboratories must require implementation of all obligations of this appendix applicable to HHS-certified laboratories.

Dated at Rockville, Maryland, this _____ day of _____, 2000.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

ATTACHMENT C

**LISTING OF RECOMMENDED MODIFICATIONS
TO PROPOSED REVISIONS TO 10 CFR PART 26**

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LISTING OF RECOMMENDED MODIFICATIONS TO PROPOSED REVISIONS TO 10 CFR PART 26

This listing discusses 28 potential modifications or revisions to the Nuclear Regulatory Commission's (NRC) proposed amendments to the fitness-for-duty rule, 10 CFR Part 26. With one exception, these potential modifications result from public comments on the proposed amendments to Part 26 that the NRC published on May 9, 1996 (61 FR 21105). The one exception, a proposed new section 26.2(e), was withdrawn because of recent changes to 10 CFR 50.82. All of the many proposed modifications contained in the public comments were carefully considered and responded to in the preparation of a comments and responses document (Attachment D to this rulemaking package). The 28 modifications or revisions included in this document represent those that were identified as potentially warranting adoption. However, some minor administrative revisions that are recommended for adoption are not included in this document. For example, the term used by the Department of Health and Human Services (HHS) for the chain-of-custody form, the custody-and-control form, will now be used in the rule where appropriate. Another example is a relaxation of requirements which allows alcohol breath analysis equipment to conform to previous, current, or future National Highway Traffic Safety Administration (NHTSA) standards. These and similar minor changes are not covered in this document. For each potential modification or revision, this listing provides a description of the potential modification, the background to the potential modification, the summary comments from the comment response document related to the change, the expected effect of the modification or revision on the industry, a recommendation, and the actual wording of the rule as currently proposed and as it would be edited to incorporate the potential modification. In addition to the 28 recommended for adoption, an additional 19 potential modifications were identified as warranting additional research and analysis but were not recommended for adoption. These are discussed in Attachment A of this document. In some cases the significant change is not recommended but a minor administrative revision is recommended. These are also shown in Attachment A. Other changes recommended by commenters but not recommended for adoption by the staff are discussed in the NUREG containing comments and responses.

Report Organization

The potential modifications are presented individually in the approximate order that any modification or revision would occur in 10 CFR Part 26. For each potential modification or revision, information is provided in the following categories:

Potential Modification: This section notes the primary section of the rule that would be changed and briefly summarizes the proposed modification.

Background: This section provides a synopsis of the commenters' concerns, some commentary on the modification, and the rationale behind the suggested modification.

Related Summary Comments: This section lists the summary comments in the comment response document that may be related in some way to the consideration of the modification.

- Effect on Industry:* This section provides a very brief assessment of whether there would be an increase-in-burden effect on industry due to the modification. In cases where the modification is intended to clarify language in the proposed revision or where the change decreases burden, the modification is described as having no effect on industry, since the modification would not have an economic effect on the proposed requirements.
- Recommendation:* This section provides the recommendation regarding whether the proposed modification should be adopted or adopted with revisions.
- Rule Reference:*
- a) The proposed revision to the rule as presented in Attachment B to SECY-95-262.
 - b) The recommended modifications to the proposed revised rule, shown as **bolded**.

**LISTING OF RECOMMENDED MODIFICATIONS TO
PROPOSED REVISIONS TO 10 CFR PART 26**

1. Section 26.2(a)(4) — Scope

Potential Modification:

Revise Section 26.2(a)(4) to more specifically explain what types of FFD program personnel would be included within the rule's scope. This change would reduce the number of FFD program personnel that would be added to the scope of the rule by Section 26.2(a)(4) as originally proposed.

Background:

Several commenters suggested that the NRC's proposal to expand the scope of the rule to include FFD program personnel was too broad. As originally proposed, Section 26.2(a)(4) would subject to the rule's requirements EAP counselors and people who make removal or return-to-work recommendations or decisions. Some commenters recommended that EAP personnel be omitted from the rule's scope citing the difficulty of testing EAP staff who are off site or contracted through health maintenance organizations. Another commenter recommended that only those FFD program personnel who make removal or return-to-work decisions, and not those who make only recommendations, should be covered by Part 26.

The purpose of Section 26.2(a)(4) as originally proposed was to include within the rule's scope FFD personnel who are key to ensuring the integrity of the FFD program. The intent of the modification would be to clarify this intent while more clearly delimiting the FFD personnel to be covered to those who are involved in the selection and notification of people to be tested, can link test results to tested employees prior to MRO determination of FFD policy violations, make management or medical determinations of fitness, and make removal and return-to-duty decisions.

Related Summary Comments: 5.2.1

Effect on Industry:

By limiting the types of FFD program personnel who would be added to the rule's coverage, this new revision would reduce licensees' administrative burden. It would also reduce licensees' costs for drug and alcohol testing that would be incurred from those that would be incurred if this section were to be revised as originally proposed.

Recommendation:

Adopt this change. The new wording would more clearly define what types of FFD program personnel should be included in the scope. This change would eliminate the need to include in the rule's coverage off-site EAP personnel and those who make only recommendations for removal and return-to-work actions.

Rule Reference:

Proposed rule in FR:

(4) FFD program personnel who:

- (i) Can link test results with the person who was tested;
- (ii) Make removal and return-to-work recommendations or decisions;
- (iii) Are involved in the selection and notification of employees for testing and in the collection and on-site testing of specimens.

Recommended modification to proposed rule:

(4) FFD program personnel who:

- (i) Can link test results with the person who was tested prior to determination of a FFD policy violation;
- (ii) Make medical or management determinations of fitness;
- (iii) Make removal or return-to-work decisions;
- (iv) Are involved in the selection or notification of employees for testing or in the collection or on-site testing of specimens.

2. Section 26.2(e) - Scope

Potential Modification:

As published in the May 9, 1996 Federal Register notice, the proposed new section 26.2(e) would have specified that Part 26 requirements apply to facilities in the process of being decommissioned. To respond to recent changes to 10 CFR 50.82, the NRC's decommissioning rule, the staff considered proposing that the new proposed Section 26.2(e) should be revised to make it clear that Part 26 requirements continue to apply to nuclear power reactor licensees that are no longer authorized to operate or retain fuel in their reactors when the Commission deems that there is a need to protect against ionizing radiation resulting from activities conducted under Part 20 licenses. It would have also noted that the FFD program shall be continued until a reduced scope program is deemed appropriate by the NRC. Upon reconsideration, the staff believes that the issue of FFD applicability to decommissioning plants should not be resolved in this FFD rulemaking. Rather, the issue of FFD applicability should be resolved as part of decommissioning regulatory improvement initiative under which the staff will reassess the technical and regulatory bases for applicability of the Commission's 10 CFR Part 50 regulations for operating nuclear power plants. Therefore, the Staff has withdrawn this proposed revision.

Background:

This revision was not being proposed in response to public comments. Instead, the staff was considering this revision to make Part 26 consistent with changes to 10 CFR 50.82, the NRC's decommissioning rule (62 FR 39058, July 21, 1997), published after the proposed changes to Part 26 were published.

The purpose of both the originally proposed and the revised version of Section 26.2(e) would have been to make sure that licensees continue to meet FFD program requirements to the extent necessary to protect public health and safety after they cease operating their reactors. Until Section 50.82 was recently adopted, the current wording in Section 26.2(a) that stipulates that Part 26 requirements "apply to licensees authorized to operate a nuclear power reactor" provided a sufficient legal basis for application of FFD requirements to decommissioning activities. Experience with decommissioning situations thus far has indicated that, while continuation of FFD program activities is desirable to assure that public health and safety is adequately protected, the scope of the programs can be reduced to people and specified areas as compared with the rule's coverage while reactors are operating. The Commission has granted licensees exemptions to Part 26 requirements to allow reduced-scope programs in these situations.

Related Summary Comments: There were no public comments on this issue.

Effect on Industry:

Because it would have continued the situation in which licensees are required to maintain at least reduced-scope FFD programs during decommissioning, this new Section 26.2(e) would have had no impact on regulatory burden.

Recommendation:

Do not adopt the change in this particular rulemaking. Instead, reserve Section 26.2(e) for potential future use.

Rule Reference:

Proposed rule in FR:

(e) The regulations in this part apply to facilities in the process of being decommissioned; however, the scope of a fitness-for-duty program may be reduced to persons and specified areas as deemed appropriate by the NRC to protect public health and safety.

Modification to proposed rule that the staff was considering:

(e) The regulations in this part apply to nuclear power reactor licensees no longer authorized to operate or retain fuel in their reactors (10 CFR 50.82(a)(2)) when the NRC deems that there is a need to protected against ionizing radiation resulting from activities conducted under licenses issued by the NRC (10 CFR Part 20); however, the scope of a fitness-for-duty program may be reduced to persons and specified areas as deemed appropriate by the NRC to protect public health and safety. The FFD program required by 26.2(a) shall be continued until the reduced scope program, as deemed appropriate by the NRC, has been implemented.

Recommended modification to proposed rule:

(e) [RESERVED]

3. Section 26.2(f) — Scope

Potential Modification:

Section 26.2(f) would allow licensees to accept tests from other federal or state testing programs if such tests “meet the general performance objectives of this part.” The recommended modification would eliminate the requirement that programs “meet the general performance objectives” and would restrict the acceptance to federal and state programs meeting certain specific requirements.

Background:

Although there was considerable support for the NRC's proposal to accept other testing programs, many commenters thought that requiring a program to meet the general performance objectives of this part would eliminate any potential benefit from this rule revision. Commenters argued that this would prevent anyone from being able to accept any other test results because of differences in the testing programs that could be interpreted as “not meeting the performance objectives of this part.” The first approach considered was that, rather than attempting to describe how other programs may or may not meet the general performance objectives of Part 26, the reference to meeting general performance objectives should be omitted. In addition, because state programs vary more widely than do federal programs, the rule would not allow state program elements to be accepted under Part 26. A number of difficulties were identified with this approach. Commenters had requested guidance regarding lack of random testing, lack of alcohol testing, and other program elements missing from programs that would be accepted under this provision. Addressing these issues highlighted difficulties with the first approach considered. An alternative approach is now recommended. This approach is to specify that NRC program elements must be maintained and that certain standards for acceptance must be met, including use of laboratories certified by HHS, the College of American Pathologists, or other comparable certification program for urine testing; awareness training; random, for-cause, and preaccess testing for the five drugs specified by HHS guidelines and for alcohol; removal from duty after a violation; impartial appeals and notification of the licensee of any violation. If another program fails to meet any of these program elements, the licensee can provide the “missing” elements. Both federal and state programs meeting these requirements would be included. Another restriction considered, but not adopted at this time, was to limit the application of this provision to licensee employees. This would reduce concerns that licensees would not have information regarding any history of substance abuse among individuals having unescorted access but covered under another program.

Related Summary Comments: 4.1.1; 4.1.2; 4.1.3; 4.1.4; 4.1.5; 4.1.8

Effect on Industry:

This new change would increase guidance and reduce concerns about appropriately implementing the NRC's proposed burden reduction.

Recommendation: Adopt the change.

Rule Reference:

Proposed rule in FR:

(f) Persons performing activities under this part who are covered by a program regulated by another Federal agency or State that meets the general performance objectives of this part need only be covered by those aspects of a licensee's fitness-for-duty program not included in the Federal agency or state program.

Recommended modification to proposed rule:

(f) Persons performing activities under this part who are covered by a program regulated by another Federal agency or State need be covered by only those elements of a licensee's fitness-for-duty program not included in the Federal agency or state program as long as all such persons are subject to pre-access (or pre-employment), random, and for-cause urine testing for the drugs specified in the Department of Health and Human Services (HHS) Mandatory Guidelines and breath testing for alcohol at or below NRC mandated cut-off levels; have their urine specimens tested at a laboratory certified by HHS, the College of American Pathologists or other comparable certification program; have awareness training covering the subjects listed in § 26.21 (a) (1), (2), (3), and (5); and access to an impartial and objective procedure for appealing any findings of a FFD violation. Provisions for notification of the licensee(s) granting unescorted access of any FFD violation by the testing agency or organization must be in place.

4. Section 26.3 — Definitions: Abuse of Legal Drugs

Potential Modification:

Revise the second sentence of the definition of abuse of legal drugs in Section 26.3 to omit the term “a health or safety hazard” and replace it with “the abuse of legal drugs.”

Background:

Commenters felt that legal and employment actions against an individual do not necessarily constitute a “health or safety hazard”. The phrase is not necessary for this definition to be effective.

Related Summary Comments: 6.1.1

Effect on Industry: There would be no impact on the industry.

Recommendation: Make this revision to the definition.

Rule Reference:

Proposed rule in FR:

Abuse of legal drugs means the use of a legal drug (e.g., alcohol, prescription, over-the-counter drugs) in a manner that constitutes a health or safety hazard to the individual or to others, including on-the-job impairment. Legal or employment actions against an individual for use of legal drugs constitute evidence of the existence of a health or safety hazard.

Recommended modification to proposed rule:

Abuse of legal drugs means the use of a legal drug (e.g., alcohol, prescription, over-the-counter drugs) in a manner that constitutes a health or safety hazard to the individual or to others, including on-the-job impairment. Legal or employment actions against an individual for use of legal drugs are examples of evidence of the abuse of legal drugs.

5. Section 26.3 — Definitions: History of Substance Abuse

Potential Modification:

Add a definition of “history of substance abuse” to Section 26.3.

Background:

A number of commenters were confused about what a “history of substance abuse” should include. The new definition would clarify the NRC's intent regarding what constitutes a history of substance abuse.

Related Summary Comments: 6.5.3

Effect on Industry: There would be no effect on the industry.

Recommendation: This definition should be adopted.

Rule Reference:

Proposed rule in FR: No definition currently exists or was proposed.

Recommended modification to proposed rule:

History of substance abuse means having violated a FFD policy and been removed from activities covered by this part at any time or, during the past five years, having (i) used, sold, or possessed illegal drugs; (ii) abused legal drugs; (iii) subverted or attempted to subvert a drug or alcohol testing program; (iv) refused to take a drug or alcohol test; (v) been subjected to a plan for substance abuse treatment (except for self-referral); or (vi) had any legal or employment action taken for alcohol or drug use.

6. Section 26.3 — Definitions: Unconfirmed Positive Test Result

Potential Modification:

Change the term to be defined from "unconfirmed positive test result" to "presumptive positive screening test result."

Background:

A number of terms are used in the original rule and elsewhere to refer to a positive drug or alcohol screening test result that has not yet been subjected to confirmatory testing. The term "unconfirmed positive test result" was proposed as a means of creating one term to use throughout the rule. However, public comments have indicated that this term would be a poor solution to this problem. To some people, "unconfirmed positive test result" appears to imply a screening test result that was ultimately not confirmed by GC/MS.

Since HHS now uses, but does not define, the term "presumptive positive" in its Mandatory Guidelines, and this term is also commonly used and understood among drug and alcohol testing program administrators and staff, the term "presumptive positive screening test result" will be commonly understood.

Related Summary Comments: 6.3.5; 6.3.6; 6.3.7

Effect on Industry: None

Recommendation: Revise the term used for this definition.

Rule Reference:

Proposed Rule in FR:

Unconfirmed positive test result means the result of a screening test for drugs and drug metabolites that indicates the presence of some drug or drug metabolite and that has the potential to be confirmed through GC/MS testing by an HHS-certified laboratory as a laboratory confirmed positive test result, or the result of a screening test for alcohol indicating a blood alcohol content of 0.02 percent or greater.

Recommended modification to proposed rule:

Presumptive positive screening test result means the result of a screening test for drugs and drug metabolites that indicates the presence of some drug or drug metabolite and that has the potential to be confirmed through gas chromatography/mass spectrometry (GC/MS) testing by an HHS-certified laboratory as a laboratory confirmed positive test result, or the result of a screening test for alcohol indicating a BAC of 0.02 percent or greater.

7. Section 26.24(a)(2) — Chemical Testing: Testing Workers Upon Return to Duty

Potential Modification:

Add language to Section 26.24(a)(2) to make clear the intended flexibility with regard to the exact timing of testing workers returning to the site after being absent from the possibility of being tested. Also, include a discussion in the Statement of Considerations (SOC) providing guidance about how to handle situations in which a worker has missed several cycles of tests because of being off-site.

Background:

This change would respond to some comments to the effect that requiring off site people to be tested “upon returning to the site” if they have been chosen for random testing would create an unnecessary burden on licensees. Some commenters believe that the proposed revision would require licensees to have FFD staff constantly on site.

Related Summary Comments: 7.2.1; 7.2.2; 7.2.5; 7.2.6

Effect on Industry:

None. The change would clarify flexibility to the industry but not result in any new costs or savings.

Recommendation:

“Upon returning to site” should be replaced by “at the earliest reasonable and practical opportunity.” Also, the first sentence of this section should be edited to make it grammatically similar to the other sections that create testing requirements.

Rule Reference:

Proposed rule in FR:

(2) Unannounced drug and alcohol tests must be imposed in a statistically random and unpredictable manner so that all persons in the population subject to testing have an approximately equal probability of being selected and tested. Random testing must include testing during all types of work periods, including weekends, backshifts, and holidays. The tests must be administered so that a person completing a test is immediately eligible for another unannounced test. At a minimum, tests must be administered on a nominal weekly frequency and at various times during the day. Reasonable efforts must be made to test persons selected for random testing. Persons off site when selected for testing, and not reasonably available for testing in a timely manner, must be tested upon returning to the site. For persons off site for more than sixty days, such tests will fulfill the requirement for return-to-duty testing and should be reported to the NRC as random tests. Random testing must be conducted at an annual rate equal to at least 50 percent of the workforce.

Recommended modification to proposed rule:

(2) Random drug and alcohol testing must be unannounced and imposed in a statistically random and unpredictable manner so that all persons in the population subject to testing have an approximately equal probability of being selected and tested. Random testing must include testing during all types of work periods, including weekends, backshifts, and holidays. The tests must be administered so that a person completing a test is immediately eligible for another unannounced test. At a minimum, random tests must be administered on a nominal weekly frequency and at various times during the day. Reasonable efforts must be made to test persons selected for random testing. Persons off site when selected for testing, and not reasonably available for testing in a timely manner, must be tested at the earliest reasonable and practical opportunity and without notification to the individual until immediately prior to his or her reporting for the test. Such tests will fulfill any return-to-duty testing required for such persons and must be reported to the NRC as random tests. Random testing must be conducted at an annual rate equal to at least 50 percent of the workforce.

8. Section 26.24(a)(3) — Chemical Testing: Delete "Attempts to Subvert" from For-Cause Testing

Potential Modification:

Delete "attempts to subvert the testing process" from Section 26.24(a)(3) as a reason to require testing for cause.

Background:

Commenters contended that the wording is redundant since attempts to subvert are indications of possible substance abuse. If subversion is suspected, a test result will not necessarily prove or disprove the subversion. Further, a negative test result may undermine the determination of a violation due to subversion. Furthermore, Sections 2.4(f), 2.4(g)(15), and 2.7(e) cover the various situations involving subversion attempts and require collecting another specimen under direct observation.

Related Summary Comments: 7.3.2

Effect on Industry: There would be no effect on the industry.

Recommendation:

This deletion should be made. The SOC accompanying the final rule should explain that, while for-cause testing may not be necessary in all cases, licensees should thoroughly determine the circumstances surrounding the subversion attempt and take whatever corrective action is necessary. Also, the numbering of this section should be revised to make it conform to the numbering in other similar sections.

Rule Reference:

Proposed rule in FR:

(3) (i) For-cause drug and alcohol testing must be conducted:

(A) Following any observed behavior or physical condition that creates a reasonable suspicion of possible substance abuse including attempts to subvert the testing process;

Recommended modification to proposed rule:

(3) (i) For-cause drug and alcohol testing must be conducted:

(A) Following any observed behavior or physical condition that creates a reasonable suspicion of possible substance abuse ;

9. Section 26.24(a)(3) — Chemical Testing: Time Limits for For-Cause Testing

Potential Modification:

Provide flexibility to Section 26.24(a)(3)(ii) which specifies time limits in for-cause testing and assure that a positive for-cause test that was not conducted within the time period specified in the rule would still be considered a valid test result. Changes to this section would also make it clear that both managers and medical personnel need to evaluate fitness.

Background:

The intent of the revised rule was to encourage licensees to conduct the for-cause test before the individual has a chance to “flush” his/her system or metabolize the substance to below the concentration specified in the cut-off level. A commenter noted that an individual who had a positive test where the specimen was collected after the specified period might be able to have the results declared invalid. We need to make sure the wording reflects the intent and doesn't make this possible.

Related Summary Comments: 7.3.3

Effect on Industry: There would be no effect on the industry.

Recommendation: This flexibility should be provided.

Rule Reference:

Proposed rule in FR:

(ii) The individual's unescorted access status must be suspended until pronounced fit for duty based on a medical determination of fitness. If the test is based on suspected use of alcohol and the breath analysis is negative, the individual, if determined fit for duty by a medical determination of fitness, may be returned to duty pending results of urinalysis for drugs. For-cause drug and alcohol testing must be conducted as soon as practicable, but within no more than 2 hours for an alcohol test and 8 hours for specimen collection for a drug test.

Recommended modification to proposed rule:

(ii) The individual's unescorted access status must be suspended until the individual is pronounced fit for duty based on a management and medical determination of fitness. If the test is based on suspected use of alcohol and the breath analysis is negative, the individual, if determined fit for duty by a medical determination of fitness, may be returned to duty pending results of urinalysis for drugs. For-cause drug and alcohol testing must be conducted as soon as practicable after the occurrence of the event. Except under documented unusual circumstances, such testing must be conducted within no more than 2 hours for an alcohol test and 8 hours for specimen collection for a drug test.

10. Section 26.24(a)(4) — Return-to-Duty Testing

Potential Modification:

Revise Section 26.24(a)(4)(ii) to include employees whose access has been removed for a violation of FFD policy involving subversion or attempted subversion of the testing process.

Background:

Section 26.24(a)(4)(ii) currently creates follow-up testing requirements for employees who are granted unescorted access after previously having had their access revoked under Section 26.27(b)(3) or (b)(4). A proposed change to Section 26.27(c) would require licensees to make acts or attempted acts of subversion of the testing process violations of their FFD policy. This proposed revision would also require that employees who are found to have subverted the testing process have their access revoked for a minimum of three years. This newly proposed administrative change to Section 26.24(a)(4)(ii) would include people who are granted unescorted access after previously having had their access revoked for acts of subversion under the follow-up testing requirements.

Related Summary Comments:

None; this is an administrative change proposed on the staff's initiative.

Effect on Industry:

There would be no effect on industry because all employees who are granted unescorted access after having their access removed have been subject to follow-up testing.

Recommendation: Adopt this change.

Rule Reference:

Proposed rule in FR:

(4) Follow-up testing must be conducted on an unannounced and unpredictable basis to verify continued abstention from the use of substances as covered under this part. An individual

(i) Whose unescorted access is reinstated after a suspension under § 26.27 (b) (3), or

(ii) Is granted unescorted access after removal under § 26.27 (b) (3) or (4) must be subject to follow-up testing that is tailored to the individual's medical history but not less frequently than once every month for four months and at least once every three months for the next two years and eight months after unescorted access is reinstated.

Recommended modification to proposed rule:

(4) Follow-up testing must be conducted on an unannounced and unpredictable basis to verify continued abstention from the use of substances as covered under this part. An individual must be subject to follow-up testing that is tailored to the individual's medical history but not less frequently than once every 30 days for four months after unescorted access is reinstated and at least once every 90 days for the next two years and eight months if:

(i) unescorted access was reinstated after a suspension under § 26.27 (b) (3), or

(ii) unescorted access will be reinstated for that individual after removal under § 26.27 (b) (3), (b) (4), or (c).

11. Section 26.24(h) — Chemical Testing: Extrapolation

Potential Modification:

Change Sections 26.24(h) and 2.9(h) (and the definition of "confirmed positive test" in Section 26.3) to replace the requirement for extrapolation with a set requirement for BAC levels of 0.02 to 0.04 percent after one or more hours on work status. The requirement would be based on a standard scale such that a BAC of 0.04 percent or greater upon arrival, 0.03 percent or greater after one hour on duty, or 0.02 percent or greater after two or more hours on duty would be a violation. The discussion in the FRN would remind licensees to make sure employees are aware of individual differences in metabolism, the effects of food, etc.

Background:

Commenters contended there are a number of problems with extrapolation. Use of extrapolation was considered difficult and undesirable by many commenters. While NRC staff continues to believe that use of extrapolation techniques is valid and legally defensible, the logistical difficulties of requiring an MRO to do extrapolation create inefficiencies. However, the staff needs to address the Commission's request for a process, such as extrapolation of BAC, to correct situations where individuals have been at work for a period of time and no action is taken by the licensee because the alcohol has metabolized below 0.04 percent BAC. The proposed standard would minimize any potential that an individual would have a positive test result without having either had a BAC of higher than 0.04 percent when in a work status or consuming alcohol while in a work status. It would also be less difficult logistically and less costly for licensees than BAC extrapolation because MROs would not have to be involved making this calculation.

Related Summary Comments: 10.2.1; 10.2.2; 10.2.3; 10.2.4; 10.3.4

Effect on Industry: The change would be easier to implement and administer.

Recommendation: Adopt this change.

Rule Reference:

Proposed rule in FR:

26.24 (h) Tests for alcohol must be administered by breath analysis using breath alcohol analyses devices meeting evidential standards described in Section 2.7 (p) (3) of Appendix A to Part 26. If the screening test shows a breath alcohol content indicating a BAC of 0.02 percent or greater, a confirmatory test for alcohol must be performed using another breath measurement instrument. A confirmatory test result showing a breath alcohol content indicating a BAC between 0.02 percent and 0.04 percent must be forwarded to the MRO for evaluation as described in Section 2.9(h) of Appendix A to Part 26. A confirmatory test for alcohol indicating a blood alcohol concentration (BAC) of 0.04 percent or greater must be declared a positive test. Further testing for alcohol must be administered if demanded by the individual for the purposes of obtaining additional information that could be considered during an appeal pursuant to § 26.28. Any such

test must be a gas chromatography analysis of blood performed on a blood specimen drawn, with the consent of the individual, promptly after the confirmatory breath analysis. Any detectable quantity of alcohol in the blood specimen may be considered, including extrapolation back in time, to determine if a violation of the FFD policy occurred.

2.9 (h) Breath alcohol content indicating a blood alcohol concentration between 0.02 percent and 0.04 percent must be reported to the MRO for review and evaluation. The MRO shall determine whether it is appropriate to extrapolate back in time to estimate the highest BAC that the worker had while on duty with the assumption that no alcohol was consumed while on duty. In these cases, the MRO will calculate a range of possible peak BACs that could have existed while the worker was on duty and make a determination whether the result is a confirmed positive test for alcohol. A similar extrapolation process must be conducted for the results of an analysis of a blood specimen for alcohol, as provided by § 26.24(h).

26.3 Definition of "confirmed positive test."

Confirmed positive test means a laboratory confirmed positive test result that has been verified as a violation of FFD policy by the Medical Review Officer (MRO) after evaluation. A "confirmed positive test" for alcohol is obtained as a result of a confirmation of blood alcohol levels of 0.04 percent or higher with a second breath analysis without MRO evaluation or as the result of an extrapolation back in time (back calculation) performed by the MRO.

Recommended modification to proposed rule:

26.24 (h) Tests for alcohol must be administered by breath analysis using breath alcohol analysis devices meeting evidential standards described in § 2.7 (p) (3) of Appendix A to part 26. If the screening test shows a blood alcohol concentration (BAC) of 0.02 percent or greater, a confirmatory test for alcohol must be performed using another breath alcohol analysis device. A confirmatory test for alcohol indicating a BAC of 0.04 percent or greater must be declared a positive test. A confirmatory test result showing a BAC of 0.02 percent or greater after the individual has been in a work status for two (2) or more hours or a BAC of 0.03 percent or greater after an individual has been in a work status (including any breaks for rest, lunch, dental/medical appointments, etc.) for more than one (1) hour must also be declared a positive test. Further testing for alcohol must be through analysis of blood specimens, and must only be administered if requested by the individual for the purposes of obtaining additional information that could be considered during an appeal pursuant to § 26.28. Such a test must be a gas chromatography analysis of whole blood performed on a blood specimen drawn as soon as possible after the confirmatory breath analysis. Any alcohol in the blood specimen may be considered together with the elapsed time between the confirmatory test and the collection of the blood specimen.

2.9 (h) Delete this section.

26.3 Definition of "confirmed positive test."

Confirmed positive test means a laboratory confirmed positive test result that has been verified as a violation of FFD policy by the Medical Review Officer (MRO) after evaluation. A "confirmed positive test" for alcohol is obtained as a result of a confirmation of blood alcohol concentration (BAC) levels of 0.04 percent or higher or a BAC of 0.02 percent or higher after an

individual has been in a work status for two (2) or more hours or a BAC of 0.03 percent or higher after an individual has been in a work status for more than one (1) hour with a second breath analysis without MRO evaluation.

Note: The following conforming change to Section 26.27(b)(2)(ii) will also be made:

(2) Lacking any other evidence to indicate the use, sale, or possession of illegal drugs or use of alcohol on site, the following must be presumed to be an indication of offsite drug or alcohol use in violation of the company FFD policy:

(i) A laboratory confirmed positive test result that is verified by the MRO as a policy violation; or

(ii) A confirmatory breath test for alcohol that indicates the individual had a BAC that violated the standards established in §26.24 (h) during any scheduled working tour.

12. Section 26.27(a) — Management Actions and Sanctions: Suitable Inquiry

Potential Modification:

Revise the suitable inquiry requirements of Section 26.27(a) to increase consistency with related access authorization requirements of 10 CFR 73.56.

Background:

Commenters generally agreed that the FFD rule's suitable inquiry requirements should be made more consistent with those of the access authorization rule. They recommended that licensees be authorized to grant employees temporary unescorted access pending final completion of the full, five-year suitable inquiry. The commenters disagreed, however, on when in the suitable inquiry process temporary unescorted access may be granted. Two commenters recommended that section be revised to authorize licensees to conduct a suitable inquiry into employees' activities over the past year and that licensees be allowed to grant temporary unescorted access after completion of that one-year suitable inquiry. In these commenters' view, this requirement would be consistent with the background investigation requirements for temporary unescorted access contained in Regulatory Guide 5.66 and 10 CFR 73.56. Another commenter recommended that licensees be authorized to grant permanent unescorted access upon initiation of the full, five-year suitable inquiry.

Based upon information obtained after publication of the proposed rule, the NRC has decided to withdraw the provision that would no longer require licensees to conduct a suitable inquiry for instances in which an applicant was not covered by an FFD program for periods of employment of 30 days or less. Licensee FFD personnel have indicated to the NRC that adverse FFD information is frequently obtained through checks of employment of 30 days or less. In those cases, employment was terminated for cause (oftentimes for substance abuse) before 30 days. Licensee FFD personnel also pointed out that under the proposed rule, employees could conceal their FFD problems by ensuring that their employment at any one site is less than 30 days, thereby avoiding both FFD testing as well as minimizing the possibility that a subsequent licensee would discover any previous for-cause termination occurring within the thirty-day period of previous employment. Furthermore, based upon the comments of the FFD personnel, the NRC now believes that there may be a concern with the employee who moves from one job to another after being terminated repeatedly for cause prior to 30 days. For these reasons, the NRC believes that a relaxation from the current requirement of conducting a suitable inquiry for all periods of employment would increase the risk to public health and safety. Accordingly, the NRC withdraws the proposed rule's provision allowing a licensee to skip a suitable inquiry for periods of employment of 30 days or less. This will avoid a situation in which workers have gaps in employment/unemployment during which employer knowledge regarding behavior affecting trustworthiness and reliability may be effectively concealed or otherwise not detected by the licensee's program. The NRC notes that the current requirement for a suitable inquiry does not apply to current employees who are temporarily away from the site and therefore not subject to a FFD program; instead the return-to-work provisions in the final rule in Section 26.27 apply to those employees who have not been subject to the licensee's FFD program for a period greater than 60 days. Finally, the NRC recognizes that obtaining information from short-term employers has sometimes proven difficult, especially when such employment is outside the nuclear power industry. The current

wording of § 26.27 that requires licensees to complete suitable inquiries “on a best-efforts basis” provides licensees with sufficient flexibility when obtaining such information becomes too burdensome.

Related Summary Comments: 8.1.2; 8.2.2; 8.2.7

Effect on Industry:

This change would provide some reduction in burden due to increased flexibility and consistency with the Access Authorization rule.

Recommendation:

Adopt a change that would authorize the granting of temporary unescorted access when the licensee has received and evaluated the past year's suitable inquiry results or has documented its best efforts to do so. Delete the sentence permitting licensees not to conduct a suitable inquiry for any period of 30 days or less that an applicant was not covered by an FFD program.

Rule Reference:

Proposed rule in FR:

(4) If a record of the type described in paragraphs (a) (1), (2), and (3) of this section is established which raises a concern about the person's history of alcohol or drug use, the new assignment to activities within the scope of this part or granting of unescorted access must be based upon a management and medical determination of fitness for duty and the establishment of an appropriate follow-up testing program, as specified in § 26.24 (a) (4). The restrictions of paragraph (b) of this section must be observed. To meet the suitable inquiry requirement, the identity of persons denied unescorted access or removed under the provisions of this part and the circumstances for the denial or removal, including test results, will be made available in response to a licensee's, contractor's, or vendor's inquiry supported by a release signed by the individual being investigated that authorizes the disclosure of the information. A suitable inquiry need not be conducted for any period of 30 days or less that the individual was not covered by an FFD program meeting the requirements of this part.

(5) Failure by an individual to list reasons for removal or revocation of unescorted access or failure to authorize the release of information is sufficient cause for denial of unescorted access. Temporary unescorted access pursuant to 10 CFR 73.56 may not be affected by this part provided that the applicant for unescorted access passes a chemical test conducted according to the requirements of § 26.24(a)(1).

(6) No section currently.

Recommended modification to proposed rule:

Delete the last sentence in Section 26.27(a)(4), delete the last sentence in Section 26.27(a)(5), and create new Sections 26.27(a)(6) and (7) as follows:

(4) If a record of the type described in paragraphs (a) (1), (2), and (3) of this section is established which raises a concern about the person's history of alcohol or drug use, the new assignment to activities within the scope of this part or granting of unescorted access must be based upon a management and medical determination of fitness for duty and the establishment of an appropriate follow-up testing program, as specified in § 26.24 (a) (4). The restrictions of paragraph (b) of this section must be observed; these restrictions include return-to-duty testing, determination of fitness, and proof of abstinence. To meet the suitable inquiry requirement, the identity of persons denied unescorted access or removed under the provisions of this part and the circumstances for the denial or removal, including test results, will be made available in response to a licensee's, contractor's, or vendor's inquiry supported by a release signed by the individual being investigated that authorizes the disclosure of the information.

(5) Failure by an individual to list reasons for removal or revocation of unescorted access or failure to authorize the release of information is sufficient cause for denial of unescorted access.

(6) Where temporary unescorted access pursuant to 10 CFR 73.56 is to be granted to an individual, the requirements in this paragraph must also be satisfied before such access is provided:

(i) If the individual has not previously been removed for violating a licensee's FFD policy, the licensee must either comply with the requirements of this section for full unescorted access or complete a suitable inquiry to verify the accuracy of the individual's written statement obtained under paragraphs (a)(1) and (a)(2) of this section covering the past year's activities (or document its best efforts in this regard), initiate a suitable inquiry for the balance of the past five years and administer a drug and alcohol test in accordance with the requirements of §26.24(a)(1). In making the suitable inquiry covering the past year's activities, the licensee may use information received over the telephone if a record of the contents of the telephone call is made and retained, or information received by electronic means such as facsimile or e-mail.

(ii) If the individual has been previously removed for violating a licensee's FFD policy, the temporary access provisions of 10 CFR 73.56 are not applicable and cannot be utilized.

(7) If an individual is returning to a licensee after an absence from the possibility of being tested under that site licensee's program for more than 60 days, the licensee must complete a suitable inquiry not later than 72 hours after unescorted access has been restored to ascertain if there was any substance abuse or other violation of a FFD policy during the absence, and must assure that the requirements for testing in accordance with §26.24(a)(5) have been satisfied. In making the suitable inquiry, the licensee may use information received over the telephone if a record of the contents of the telephone call is made and retained, or information received by electronic means such as facsimile or e-mail.

13. Section 26.27(b)(3) — Management Actions and Sanctions: Behavioral Observation During Assessment Period

Potential Modification:

Add language to Section 26.27(b)(3) to clarify that requirements for behavioral observation during an assessment period following the first FFD violation apply only to workers still under licensee employ.

Background:

Commenters have expressed concern that licensees will be responsible for behavioral observation of individuals no longer in their employ.

Related Summary Comments: 12.2.2; 12.3

Effect on Industry: This change would have no impact on the industry.

Recommendation:

Adopt these changes. One of the new revisions would be new wording intended to make it clear that employees who have been denied access because of FFD policy violations must continue to be subject to certain FFD program elements only if they remain employed by their licensee, contractor, or vendor employers. The addition of the word "applicable" would be a second new revision intended to indicate that the FFD program responsible for coverage of such employees may be either a licensee, contractor, or vendor program depending on the circumstances.

The originally proposed changes to this section include the phrase "if in a work status" to clarify that employees who have been denied access, but remain employed, must be subject to behavioral observation in cases where they are assigned a job in the employer's workplace. When such employees are suspended and do not come to the workplace, they do not have to be subject to behavioral observation. Nonetheless, all employees who are denied access and remain employed in some capacity must be subject to both chemical testing and sanctions for further FFD violations. This is true both in cases when the employee is "in a work status" at the employer's workplace or suspended and barred from being at the workplace.

Rule Reference:

Proposed rule in FR:

(3) The first violation of the FFD policy involving a confirmed positive drug or alcohol determination must, at a minimum, result in immediate removal from activities within the scope of this part for at least 14 days and referral to the EAP for assessment and counseling during any suspension period. Plans for treatment, follow-up, and future employment, if applicable, must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period. Although the individual must be removed from activities covered by this part, the individual must continue to be covered during any suspension period by the licensee's FFD

program with respect to behavioral observation if in a work status, chemical testing, and sanctions for violations of the licensee's FFD policy. Before an individual is permitted to be returned to duty or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform such activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24(a)(5) must be conducted before the individual may be returned to duty and follow-up testing under § 26.24(a)(4) must be conducted to verify continued abstinence from the use of substances. Any subsequent violation of FFD policy, including during an assessment or treatment period, must immediately result in removal from activities described in § 26.2(a) for a minimum of 3 years from the date of removal.

Recommended modification to proposed rule:

(3) The first violation of the FFD policy involving a confirmed positive drug or alcohol determination must, at a minimum, result in immediate removal from activities within the scope of this part for at least 14 days and referral to the EAP for assessment and counseling during any suspension period. Plans for treatment, follow-up, and future employment, if applicable, must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period. Although the individual must be removed from activities covered by this part, if the individual is retained by the licensee in an employment status pending reinstatement of unescorted access, the individual must continue to be covered during any suspension period by the applicable FFD program with respect to behavioral observation if in a work status, chemical testing, and sanctions for violations of the licensee's FFD policy. Before an individual is permitted to be returned to duty or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform such activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24(a)(5) must be conducted before the individual may be returned to duty and follow-up testing under § 26.24(a)(4) must be conducted to verify continued abstinence from the use of substances. Any subsequent violation of FFD policy, including during an assessment or treatment period, must immediately result in revocation of authorization to perform activities described in § 26.2(a) for a minimum of 3 years from the date of removal.

14. Section 26.71(b) and (c) — Recordkeeping Requirements: 5-Year Retention Period

Potential Modification:

Revise Section 26.71(c) to make it clear that 1) it is records pertaining to the determination of a violation of a FFD policy that are to be permanently retained, and 2) employees who have violations of a FFD policy under Sections 26.27(b)(3), (b)(4), (b)(5), and (c) must have their authorization to perform Part 26 duties revoked. Also make related changes to Section 26.27(b) and (c) and to 2.2(a) of Appendix A.

Background:

A commenter noted that the current Section 26.71(b) requirements could potentially mean that, if someone violates the rule and later seeks to regain unescorted access more than five years after the violation, there would be no record of the first violation to be provided in response to a suitable inquiry. Section 26.71(b) has always allowed licensees to discard after five years the supporting documentation that they collect in their determination of confirmed positive test results and the related personnel actions. Section 26.27(b)(3) has always required licensees to remove an employee from Part 26 activities for a minimum of three years if the employee has a second confirmed positive test result, even though that second violation occurs more than five years after the first violation. While licensees may discard the supporting documentation pertaining to such violations after five years as allowed by Section 26.71(b), they have always had to maintain a permanent record of violations to be able to comply with Section 26.27(b)(3). Therefore, it is reasonable to assume that licensees have always maintained some kind of permanent record of employees who have violated the FFD policy in, for example, their employment files or in lists of past FFD policy violators. Because this record should also be sufficient for purposes of complying with the Section 26.27(a) suitable inquiry requirements, Section 26.71(b) need not be changed to respond to the commenter's concern.

Section 26.71(c) currently requires licensees to retain records of persons made ineligible for three years or longer for assignment to duties within the scope of Part 26 until the Commission terminates the license under which the records were created. This section has never clearly stated that records to be maintained are those pertaining to the determination of FFD policy violations. Likewise, this section, and related Sections 26.27(b)(3), (b)(4), (b)(5), and (c), have been unclear as to the type of action that licensee's are to take when an employee commits a policy violation of the type covered by these sections. This lack of clarity can be remedied by revising these sections to clearly require licensees to revoke an employee's authorization to perform duties within the scope of Part 26.

In section 2.2(a) of Appendix A references to retention of custody-and-control forms have been edited to agree with changes to 26.71(b) and (c).

Related Summary Comments: 17.1.2

Effect on Industry:

No impact. Licensees are retaining under Section 26.71 all employment records related to violations of FFD policy due to current requirements of Sections 26.27(a) and (b)(3).

Recommendation:

Revise Section 26.71(c) to clarify the types of records to be retained; make companion revisions to Sections 26.27(b) and (c) and 2.2(a) of Appendix A. Generally, change "removal from unescorted access" and "denial of" to "revocation of authorization to perform" activities described in Section 26.2. Also add wording to Section 26.71(b) to make it clear that records relevant to FFD policy violations should be retained beyond five years if there is a pending legal proceeding.

Rule Reference:

Proposed rule in FR:

(b) Retain relevant records pertaining to the determination of a violation of the FFD policy and the related personnel actions for a period of at least five years;

(c) Retain records of persons made ineligible for three years or longer for assignment to activities within the scope of this part under the provisions of § 26.27 (b) (3), (4), and (5) or (c), until the Commission terminates each license under which the records were created; and

Recommended modification to proposed rule:

(b) Retain records pertaining to the determination of a violation of the FFD policy and the related personnel actions for a period of at least five years or until completion of all legal proceedings related to the violation, whichever is later.

(c) Retain records pertaining to the determination of a violation of the FFD policy of persons whose authorization to perform activities within the scope of this part has been revoked under § 26.27 (b) (3), (4), (5) or (c), until the Commission terminates each license under which the records were created; and

Note: Related changes to Section 26.27(b)(3), (b)(4), (b)(5), and (c) would be required as follows:

Recommended modifications to Section 26.27(b)(3), (b)(4), (b)(5), and (c):

(3) The first violation of the FFD policy involving a confirmed positive drug or alcohol determination must, at a minimum, result in immediate removal from activities within the scope of this part for at least 14 days and referral to the EAP for assessment and counseling during any suspension period. Plans for treatment, follow-up, and future employment, if applicable, must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period. Although the individual must be removed from activities covered by this part, if the individual is retained by the licensee in an employment status pending reinstatement of unescorted access, the individual must continue to be covered during any suspension period by the applicable FFD program with respect to behavioral observation if in a work status, chemical

testing, and sanctions for violations of the licensee's FFD policy. Before an individual is permitted to be returned to duty or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform such activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24 (a) (5) must be conducted before the individual may be returned to duty and follow-up testing under § 26.24 (a) (4) must be conducted to verify continued abstinence from the use of substances. Any subsequent violation of FFD policy, including during an assessment or treatment period, must immediately result in revocation of authorization to perform activities described in § 26.2 (a) for a minimum of 3 years from the date of removal.

(4) Any individual determined to have been involved in the sale, use, or possession of illegal drugs or the use of alcohol while, as applicable, within a protected area of any nuclear power plant, within a facility that is licensed to possess or use SSNM, or within a transporter's facility or vehicle, must immediately have his or her authorization to perform activities within the scope of this part as described in § 26.2 (a) revoked for a minimum of 5 years from the date of revocation.

(5) Persons removed for periods of three years or more under the provisions of paragraphs (b) (2), (b) (3), (b) (4) and (c) of this section and who would have been removed under the current standards of a hiring licensee, may be granted unescorted access and assigned duties within the scope of this part by a licensee subject to this part only when the hiring licensee receives satisfactory medical assurance that the person has abstained from the use of illegal drugs and the abuse of legal drugs for at least three years. Before an individual is permitted to be returned or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform these activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24 (a) (5) must be conducted before the individual may be assigned duties and follow-up testing under § 26.24 (a) (4) must be conducted to verify continued abstinence from the abuse of substances. Any further violation of FFD policy must immediately result in permanent revocation of authorization to perform activities described in § 26.2 (a).

(c) Any act or attempted act to subvert the testing process, including refusal to provide a specimen for testing, must be a violation of the licensee's FFD policy and must result in revocation of authorization to perform activities described in § 26.2 (a) for a minimum of 3 years. Any act or attempted act to subvert the testing process, or resignation before removal for violation of company fitness-for-duty policy concerning drugs and alcohol must be recorded and provided in response to a suitable inquiry. The specific cause for a removal, e.g., that a laboratory confirmed positive test result was obtained and that the individual resigned before an MRO review, must also be provided in response to a suitable inquiry. A record of these actions must be retained consistent with § 26.71 (c) following any revocation of authorization to perform activities described in § 26.2 (a).

Recommended modifications to Section 2.2(a) of Appendix A:

(a) Use of a custody-and-control form. The original must accompany the specimen to the HHS-certified laboratory. A copy must accompany any split specimen. The form must be a record on which is retained identity data (or codes) on the individual providing the specimen and information on the specimen collection process and transfers of custody of the specimen. Custody-and-control forms related to determinations of violations of the FFD policy must be retained as required by §26.71(b) and (c), or until the completion of all legal proceedings related to the

violation, whichever is later. Custody-and-control forms recording specimens with negative test results and no FFD violations or anomalies may be destroyed after appropriate summary information has been recorded for program administration purposes.

15. Section 26.73(a)(3) — Reporting Requirements: FFD Program Integrity

Potential Modification:

Change the wording regarding the requirement to report FFD program personnel violations in Section 26.73(a)(3) to read “any act or event that would cast doubt on the integrity of the FFD program, including, but not limited to, acts that cast doubt on the honesty and integrity of FFD personnel.”

Background:

These commenters' contentions indicated a need for clarification of reporting requirements for events involving FFD program personnel and a need to confirm that the NRC continues to be concerned about the overall integrity of the FFD program.

Related Summary Comments: 17.2.2; 17.2.11

Effect on Industry: There would be no impact on the industry.

Recommendation: Adopt this change.

Rule Reference:

Proposed rule in FR:

(3) Any act that would cast doubt on the honesty and integrity of the FFD program personnel specified in § 26.2(a)(4),

Recommended modification to proposed rule:

(3) Any act that would cast doubt on the integrity of the FFD program, including, but not limited to, acts that cast doubt on the honesty and integrity of the FFD program personnel specified in § 26.2(a)(4),

16. Section 26.80(c) — Audits

Potential Modification:

Revise Section 26.80(c) to make it clear that licensees are to take corrective action in response to audit findings.

Background:

A commenter correctly noted that, as currently written, Section 26.80(c) does not clearly require licensees to take corrective action, as opposed to just documenting corrective action, to ensure that problems detected in audits are not repeated. The commenter provided new wording that paraphrases audit requirements from Appendix B to 10 CFR Part 50 and recommended that this wording be added to Section 26.80(c).

Related Summary Comments: 18.2.3

Effect on Industry:

There would be no effect on industry because this change would clarify the NRC's original intent.

Recommendation:

Adopt this change. The change would clarify the Commission's original intent that licensees take appropriate corrective action in response to audit findings.

Proposed rule in FR:

(c) The result of the audit, along with recommendations, if any, must be documented and reported to senior corporate and site management. The resolution of the audit findings and corrective actions must be documented. The documents must be retained for three years.

Recommended modification to proposed rule:

(c) The result of the audit, along with recommendations, if any, must be documented and reported to senior corporate and site management. The audit report must identify conditions adverse to the proper performance of the FFD program, the cause of the condition(s) and, when appropriate, recommend corrective actions. Management shall review the audit findings and take follow-up action, including re-audit of the deficient areas where indicated, to preclude, within reason, repetition of the condition. The resolution of the audit findings and corrective actions must be documented. The documents must be retained for three years.

17. Appendix A, Section 1.3 — Future Revisions and Appendix A, Section 2.7(f)(2) and (g)(4) On-Site and Laboratory Screening Tests and Confirmatory Tests

Potential Modification:

A new Section 1.3 of Appendix A would be added to Appendix A to note that the Commission expects to make adaptations to the rule in response to new technologies and information. In addition, the areas listed for ongoing review in Appendix A Section 2.7 at (f)(2) and (g)(4) would be expanded.

Background:

Although the wording in the rule only notes (at Section 2.7(f)(2) and (g)(4)) that the Commission will review and respond to information on substances and cutoff levels, it does not inform licensees of the full range of areas that are expected to change as the knowledge about and technologies for fitness for duty and drug testing expand. These additions to the rule would inform the industry that these areas are subject to re-evaluation and change on an ongoing basis.

Related Summary Comments: 19.1.3

Effect on Industry:

This change would provide the industry with notice that the NRC anticipates making changes to the rule in response to new knowledge and technologies.

Recommendation:

Adopt the new section 1.3 of Appendix A and revise Section 2.7(f) of Appendix A as written below.

Rule Reference:

Proposed rule in FR: For Section 1.3 there is no current section.

Section 2.7(f)(2). The list of substances to be tested and the cut-off levels are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant the inclusion of additional substances and other concentration levels.

Section 2.7(g)(4). The list of substances to be tested and the cut-off levels are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant the inclusion of additional substances and other concentration levels.

Recommended modification to proposed rule:

1.3 "Future Revisions." In order to adapt the rule to changes in the evolving disciplines related to substance abuse and employee fitness and ensure the full reliability and accuracy of drug assays, the accurate reporting of test results, and the integrity and efficiency of drug testing programs conducted under the provisions of 10 CFR Part 26, the Commission may make changes to these Guidelines to reflect improvements in the available science and technology, in response to additional experience, or as other considerations warrant.

Section 2.7(f)(2). The list of substances to be tested and the cut-off levels, along with the procedures, quality controls, and standards applicable to specimen collection, analysis, and validity, are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant such changes.

Section 2.7(g)(4). The list of substances to be tested and the cut-off levels, along with the procedures, quality controls, and standards applicable to specimen collection, analysis, and validity, are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant such changes .

18. Appendix A, Section 2.1(b) — Testing for Any Substance Suspected of Having Been Abused

Potential Modification:

Change wording in Section 2.1(b) of Appendix A from “illegal drugs” to “any drug included in Schedules I or II of the Controlled Substances Act”, specify that the licensee can also test for other drugs that an employee may have abused, and clarify that all these drugs can be tested for in both for-cause and follow-up testing.

Background:

These changes as proposed by commenters would include legal prescription drugs under the provisions that allow licensees to test for additional drugs. The rule elsewhere allows licensees to test for prescription drugs. For example, the rule requires licensees to test for opiates and amphetamines which can be legal under prescription. Changing this section's wording from a reference to "illegal drugs" to a reference to drugs included in Schedules I and II of the Controlled Substances Act would, however, be too limiting. There are some drugs that do not appear on Schedules I and II for which licensees may need to test. To reply to commenters' requests for clarification, the section's reference to "illegal drugs" should be left unchanged and new wording should be added to make it clear that licensees can test for other drugs they suspect are being abused.

This section currently allows licensees to test for such drugs during for-cause tests. As the commenters recommend, licensees should also have the discretion to test for illegal drugs or other drugs they suspect were abused when a person returns to duty after having been removed from access and during any test of a person who is in a follow-up testing program. Testing conducted during a follow-up testing program would include a random test if a person subject to follow-up testing is chosen from the random testing pool.

Related Summary Comments: 7.4.3, 9.5.7

Effect on Industry: The changes would provide increased clarity and consistency in the rule.

Recommendation:

Adopt these changes. However, rather than deleting "illegal drugs" and replacing it with a reference to drugs in Schedules I and II, the authority given in this section should be expanded to include testing for any substances that are suspected of having been abused.

Rule Reference:

Proposed rule in FR:

(b) Licensees may test for any illegal drugs and may consider any detected drugs or metabolites when determining appropriate action during a for-cause test or analysis of any specimen suspected of being adulterated or diluted (in vivo or in vitro), substituted, or tampered with by any other means.

Recommended modification to proposed rule:

(b) Licensees may test for any illegal drugs or any other substances suspected of having been abused and may consider any detected drugs or metabolites when determining appropriate action during a for-cause test, a return-to-duty test after removal from access under § 26.27(b) or (c), any test of an individual who is in a follow-up testing program, or analysis of any specimen suspected of being adulterated or diluted (in vivo or in vitro), substituted, or tampered with by any other means.

19. Appendix A, Section 2.4(f)(1) — Specimen Collection Procedures: Privacy

Potential Modification:

Add wording to Sections 2.4(f)(1) and (3) indicating that a prior submission of a urine specimen that was determined to be of questionable validity is a reason to believe that the employee may alter or substitute the specimen to be provided unless the MRO has determined after special processing of the prior specimen that the employee did not violate the licensee's FFD policy. Also revise Section 2.4(f)(2) to specify that submission of a urine specimen that falls outside of the normal temperature range should be grounds for requiring an observed specimen collection at a later time if the employee's oral temperature varies by more than 1°C/1.8°F from the temperature of the specimen.

Background:

The proposed new Section 2.4(f)(1) and the current Section 2.4(f)(3) allow licensees to require an observed urine specimen collection if the employee has previously submitted a specimen that was determined to be of questionable validity. The proposed new Section 2.7(e) would require licensees to subject specimens of questionable validity to be screen tested to the lowest concentration level the HHS-certified laboratory is capable of performing and, if necessary, to be confirmation tested at the laboratory's limit of detection. MRO review of the results of this special processing may in many cases, particularly in those involving dilute specimens, indicate that the specimen validity question has been adequately resolved and that there is no indication that the employee has violated the licensee's FFD policy. In such cases the questionable specimen should not compromise the employee's privacy at a later specimen collection. The proposed revisions to Sections 2.4(f)(1) and (3) would protect the employee's privacy by indicating that the previously submitted specimen of questionable validity should not constitute a reason to require a subsequent specimen collection to be observed if the MRO, after reviewing the data provided by the special processing, finds no reason to believe that there was an attempt to subvert the testing process.

Section 2.4(f)(2) currently allows licensees to require an observed urine specimen collection if 1) the employee has previously presented a urine specimen that falls outside the acceptable temperature range, and 2) the employee's oral temperature does not equal or exceed the specimen's temperature. A commenter pointed out that this wording can allow an anomalous situation in which a person with a normal oral temperature submits a specimen having a temperature below the allowable temperature range but is not subject to an observed specimen collection because they do not meet the criterion for requiring an observed specimen collection. This would be the case because the oral temperature did not equal or exceed the specimen's temperature. This proposed change would eliminate the chance for this anomalous situation by deleting the wording regarding the employee's oral temperature not being equal to or exceeding the specimen's temperature. New wording recommended by a commenter (and now used by DOT) would indicate that submission of a specimen outside of the acceptable temperature range would be grounds for requiring a subsequent collection to be observed if the employee's oral temperature varies by more than 1°C/1.8°F from the temperature of the specimen.

Related Summary Comments: 11.3.4

Effect on Industry:

These change to Sections 2.4(f)(1) and (3) would provide a minimal reduction in burden by reducing the incidence of observed specimen collection in some circumstances. The change to Section 2.4(f)(2) would have no effect because it would merely clarify currently vague wording but probably create little change in licensee testing activities.

Recommendation: Adopt these changes.

Rule Reference:

Proposed rule in FR:

2.4(f) "Privacy." Procedures for collecting urine specimens must allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided. For purposes of this appendix the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute a urine specimen:

(1) The individual has presented, at this or any previous collection, a urine specimen that fails to meet the standards for an acceptable specimen as provided in paragraph 2.4 (g) (15) of this appendix, or the specimen is determined to be of questionable validity under the provisions of paragraph 2.7 (e) of this appendix.

(2) The individual has presented a urine specimen that falls outside the normal temperature range, and the individual declines to provide a measurement of oral body temperature by sterile thermometer, as provided in paragraph 2.4 (g) (15) of this appendix, or the oral temperature does not equal or exceed that of the specimen.

(3) The last urine specimen provided by the individual (i.e., on a previous occasion) was determined to have a specific gravity of less than 1.003 or a creatinine concentration below .2 g/L.

(4) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the specimen.

(5) No change.

Recommended modification to proposed rule:

Change sections (1), (2), and (3) to read as follows:

(1) The individual has presented, at this or any previous collection, a urine specimen that failed to meet the standards for an acceptable specimen as described in § 2.4 (g) (15) of this appendix, or the specimen was determined to be of questionable validity or invalid under the provisions of § 2.7 (e) of this appendix unless it was determined by MRO review, after special processing of the specimen as provided in that section, that no violation of the licensee's FFD policy occurred.

(2) The individual has presented a urine specimen that falls outside the normal temperature range and (i) the individual declines to provide a measurement of oral body temperature by sterile thermometer, as provided in § 2.4 (g)(15) of this appendix or (ii) the individual's oral temperature varies by more than 1°C/1.8°F from the temperature of the specimen.

(3) The last urine specimen provided by the individual (i.e., on a previous occasion) was determined to have a specific gravity of less than 1.003 or a creatinine concentration below 20 milligrams per deciliter unless it was determined by MRO review after special processing of the specimen as provided in § 2.7 (e) of this appendix that no violation of the licensee's FFD policy occurred.

20. Appendix A, Section 2.4(g)(11) — Specimen Collection Procedures: Partial Specimens

Potential Modification:

Remove language in Section 2.4(g)(11) that specifies that partial specimens are to be combined and replace it with language that specifies that partial specimens are to be sent to the lab separately.

Background:

As commenters noted, combining specimens is inappropriate because one specimen, usually the first one, may be suspected of being adulterated or substituted, because combining specimens increases the possibility of contamination or error, and because combining specimens would lower the concentration of any drugs in the first specimen since there may be liquids given to the donor before he or she provides the second specimen.

Related Summary Comments: 9.5.1

Effect on Industry: The proposed change prevents potential problems.

Recommendation: Adopt this change.

Rule Reference:

Proposed rule in FR:

(11) Upon receiving a urine specimen from the individual, the collection site person shall determine that it contains a quantity of urine sufficient to meet specific licensee testing program requirements. The quantity collected must include at least 30 milliliters for the primary specimen, and a sufficient quantity for any on-site testing and testing for any additional drugs. Where collected specimens are split under the provisions of Section 2.7(k) of this appendix, an additional 15 milliliters must be collected. The total to be collected should be of sufficient quantity for all analyses and reanalyses and must be predetermined by each licensee. If there is less than the required quantity of urine in the container, additional urine must be collected to reach the required quantity. Each successive void must be collected in a separate container. (The temperature of any partial specimen in its separate container must be measured in accordance with paragraph (g) (13) of this section, and the partial specimens must be inspected and sealed as described below for a full specimen. Upon obtaining the required amount, the partial specimens must be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., normally, an 8 oz. glass of water every 30 minutes, but not to exceed a maximum of 24 oz.). If the individual fails for any reason to provide a sufficient quantity of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

Recommended modification to proposed rule:

(11) Upon receiving a urine specimen from the individual, the collection site person shall determine whether it contains a quantity of urine sufficient to meet specific licensee testing

program requirements. This quantity must be predetermined by each licensee and must take into account all analyses and reanalyses provided for in the licensee's FFD policy. The predetermined quantity for any particular specimen must include at least 30 milliliters for testing at the HHS-certified laboratory required under § 2.1 (a) of this appendix plus an appropriate additional quantity if the licensee tests for additional drugs. Where collected specimens are to be split under the provisions of § 2.7(k) of this appendix, the predetermined quantity must include at least an additional 15 milliliters. The predetermined quantity should also provide for an additional quantity for onsite testing, if the licensee conducts such testing. In cases where the specimen volume is insufficient to fulfill all analysis and reanalysis requirements as predetermined by the licensee, the specimen should be used to the extent possible to meet those requirements in the following order of priority: testing of the specimen at the HHS-certified laboratory, provision for a split specimen, and onsite screening tests. Partial specimens (less than 30 milliliters) should be retained and sent with any subsequently collected specimen(s) for testing at the HHS-certified laboratory. If there is less than the quantity of urine in the container required for HHS-certified laboratory testing, additional urine must be collected. Each successive void must be collected in a separate container. (The temperature of any specimen in its separate container must be measured in accordance with §2.4 (g) (13) of this section, and the specimen must be inspected, sealed, and labeled as described below for a specimen that meets the licensee's full volume requirements. Each specimen must be sent separately for analysis. The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., normally, an 8 oz. glass of water every 30 minutes, but not to exceed a maximum of 24 oz.). If the individual fails for any reason to provide a quantity of urine sufficient to fulfill all analysis and reanalysis requirements as predetermined by the licensee, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

21. Appendix A, Section 2.4(i) — Specimen Collection Procedures: Specimen Degradation

Potential Modification:

Revise Section 2.4(i) to state that specimens must be sent to the HHS-certified laboratory as soon as reasonably possible or appropriate and prudent steps must be taken (e.g., refrigeration) to assure that specimen degradation does not occur.

Background:

This change responds to commenters concerns about lack of flexibility. It would provide more flexibility than the revision as currently proposed and would be less prescriptive than the original version.

Related Summary Comments: 7.6.5; 9.5.3

Effect on Industry: The change would have no impact on the industry.

Recommendation: Adopt this change.

Rule Reference:

Proposed rule in FR:

(i) "Specimen Preparation and Transportation to Laboratory or Testing Facility." Collection site personnel shall arrange to transfer the collected specimens to the drug testing laboratory or licensee testing facility. To minimize false negative results from specimen degradation, specimens must be sent to the HHS-certified laboratory as soon as reasonably possible but in no case should the time between specimen shipment and receipt of the specimen at the HHS-certified laboratory exceed 48 hours, or the time between shipment and screening test at the HHS-certified laboratory exceed 72 hours. Collected urine specimens must be shipped to the HHS-certified laboratory, or cooled to not more than 6 degrees centigrade (42.8°F), within 6 hours of collection. Sealed and labeled specimen bottles being transferred from the collection site to the drug testing laboratory must be placed in a second, tamper-evident shipping container which must be designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal. The collection site personnel shall ensure that the chain-of-custody documentation is attached to each urine specimen bottle.

Recommended modification to proposed rule:

(i) Specimen Preparation for Transportation to Laboratory or Testing Facility. Collection site personnel shall arrange to transfer the collected specimens to the drug testing laboratory or licensee testing facility. Licensees shall take appropriate and prudent actions to minimize false negative results from specimen degradation. At a minimum, collected urine specimens must be shipped to the HHS-certified laboratory, or cooled to not more than 6 degrees centigrade (42.8°F), within 6 hours of collection. Specimens must be sent to the HHS-certified laboratory as soon as

reasonably possible but, except under unusual circumstances, the time between specimen shipment and receipt of the specimen at the HHS-certified laboratory should not exceed 48 hours, or the time between shipment and the screening test at the HHS-certified laboratory exceed 72 hours. The collection site personnel shall ensure that the custody-and-control form is packaged with its associated urine specimen bottle. Sealed and labeled specimen bottles, with their associated custody-and-control forms, being transferred from the collection site to the drug testing laboratory must be placed in a second, tamper-evident shipping container which must be designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal.

22. Appendix A, Section 2.7(e) — Laboratory and Testing Facility Analysis Procedures: Validity and LOD Testing

Potential Modification:

Revise this section to be more consistent with new HHS policy on dilution and adulteration testing and to clarify that all specimens must be tested for adulteration and dilution (i.e., on-site drug testing facilities must test for specimen validity, all specimens that are found to be not valid or of questionable validity shall be sent to the HHS-certified laboratory, and all specimens sent to the HHS-certified laboratory shall be tested for specimen validity).

Background:

Some commenters objected to specimen validity and LOD testing because such testing is not required by HHS and they contended that such testing is difficult, expensive, or not necessary. However, other commenters stated that 1) specimen validity testing has always been required, 2) clearer guidelines will increase consistency and decrease successful subversion, and 3) using specimen validity and LOD testing will deter attempts to subvert the testing process through dilution of specimens and will prevent unnecessary second, observed, testing for individuals with specimens which are dilute for legitimate reasons.

Prior to the publication of the rule package, HHS allowed, but did not require HHS-certified laboratories to test for adulteration and dilution. Subsequent to the publication of the proposed rule package, HHS published a notice regarding adulteration and dilution testing to HHS-certified and applicant laboratories medical review officers (NLCP Program Document #35). This document establishes recommended standards for HHS-certified laboratories testing for adulteration and dilution--including standards for levels of creatinine (and specific gravity (SG) under some conditions), pH, and nitrites. This HHS directive constitutes a policy for conducting, reporting, and interpreting drug and adulteration test results for specimens tested under federally regulated workplace drug testing programs. These changes were motivated by the reports to HHS that the number of adulterated/diluted specimens has increased. In response to these new HHS standards, the NRC has adapted this section to achieve more consistency with the new HHS policy.

Related Summary Comments: 11.1.1; 11.1.2; 11.1.3; 11.1.8; 11.1.9; 11.2.1; 11.2.2; 11.2.5; 11.2.6; 11.2.7; 11.2.9; 11.2.10; 11.4.1

Effect on Industry:

A number of commenters suggested that testing for specimen validity and using LOD testing could be very expensive. However, the figures given and the assumptions made to support this assertion are very questionable since the rule requires that specimens be checked for adulteration and dilution now. Using LOD testing instead of collecting an additional specimen under direct observation is expected to create a cost savings.

Recommendation: Revise the proposed rule section to adapt it to the new HHS policy.

Rule Reference:

Proposed rule in FR:

(e) "Determining Specimen Validity." Specimens must be tested at a licensee's testing facility, if the licensee conducts screening tests, and at an HHS-certified laboratory to determine their validity and to detect evidence of adulteration or dilution. At a minimum, such testing must include analysis of specific gravity (SG) before being subjected to screening testing. Devices used to determine validity of the specimen must be accurate and not contaminate the specimen. A specimen acceptable for testing using the cut-off levels in Section 2.7(f)(1) and Section 2.7(g)(2) has a specific gravity greater than 1.003 and is free of detectable adulterants. Specimens determined to be of questionable validity that show evidence of dilution must be subject to both screening and confirmation testing using the limit of detection (LOD) that the laboratory is capable of performing. If the specimen's specific gravity (SG) is less than 1.001, or if there is reason to believe that the specimen has been adulterated, the laboratory need not conduct LOD testing and must report the possibly adulterated or diluted condition to the Medical Review Officer. When the MRO cannot determine if the specimen is valid or invalid, another specimen must be collected as soon as possible under the provisions of Section 2.4(f).

Recommended modification to proposed rule:

(e) "Determining Specimen Validity."

(1) Licensees should take prudent and appropriate actions to assure specimen validity. Devices used to determine validity of the specimen on site and at HHS-certified laboratories must be accurate and not contaminate the specimen. At a minimum, the following actions must be taken. Equivalent processes may be used when acceptable to the HHS laboratory certification program; additional measures may be taken as changes to subversion technology take place. Specimens that are to be tested at the licensee's testing facility must first be tested for creatinine, specific gravity, pH, and nitrites. If a specimen's creatinine concentration is less than 20 milligrams per deciliter, if the specific gravity is less than 1.003, if the pH is less than 4.8 or greater than 7.8, if the nitrite concentration is equal to or greater than 500 micrograms per milliliter, or if there is other evidence of adulterants, the specimen must be sent to the HHS-certified laboratory for processing. HHS-certified laboratories must test these specimens and all other urine specimens forwarded under the provisions of § 26.24(d)(1) to determine their validity and to detect evidence of adulteration or dilution. At a minimum, such testing must include analysis for creatinine, pH, and nitrites (and specific gravity when acquisition and certification of automated methods are completed) before being subjected to screening testing. If a specimen's creatinine concentration is less than 20 milligrams per deciliter, the laboratory must measure the specimen's specific gravity.

(2) A valid specimen acceptable for testing using the cut-off levels in §§ 2.7(f)(1) and 2.7(g)(2) of this appendix, at either a licensee's testing facility or a HHS-certified laboratory, is free of adulterants and has a creatinine level equal to or greater than 20 milligrams per deciliter, a pH concentration between 4.8 and 7.8 (inclusive), a nitrite concentration less than 500 micrograms per milliliter, and a specific gravity equal to or greater than 1.003 (when applicable). Specimens not meeting these standards are to be considered either adulterated, diluted, or of questionable validity.

(3) A specimen is invalid if it is either diluted or adulterated. A specimen is invalid if it has a creatinine concentration equal to or less than 7 milligrams per deciliter in combination with a specific gravity measurement equal to or less than 1.001 or in combination with a specific gravity measurement equal to or greater than 1.020, a pH measurement equal to or less than 3.5 or equal

to or greater than 11.0, a nitrite concentration equal to or greater than 500 micrograms per milliliter, or if it has detectable adulterants. When a laboratory determines that a specimen is invalid, it need not conduct further testing but must report the possibly diluted or adulterated condition and the quantitated results of all testing to the MRO.

(4) A specimen of questionable validity is a specimen that contains no detectable adulterants but shows evidence of dilution by having a combined creatinine/specific gravity result that falls between a creatinine concentration greater than 7 milligrams per deciliter in combination with a specific gravity greater than 1.001 and a creatinine concentration of less than 20 milligrams per deciliter in combination with a specific gravity of less than 1.003, or by having a pH concentration greater than 3.5 but less than 4.8 or greater than 7.8 but less than 11.0. Specimens determined to be of questionable validity must be subject to screening testing using FDA-approved analytical kits having the lowest concentration levels marketed for the screening technology(ies) being used. The responses of questionable donor specimens must be compared to the acceptable range of negative screening control responses. Those specimens that have responses that are greater than the negative control responses must be subject to confirmation testing by GC/MS at the laboratory's limit of detection (LOD). Such testing need be conducted only for the substance(s) responded to in the screening test. Quantified test results must be reported to the MRO. Negative screening results for this special processing must be reviewed by the MRO, and, if the MRO has reason to believe that the dilution is the result of a subversion attempt, the specimen must also be subject to GC/MS testing at the laboratory's LOD.

(5) When the MRO cannot determine if the specimen is valid or invalid, another specimen must be collected as soon as possible under the direct observation of a same gender collection site person.

23. Appendix A, Section 2.7(f)(1) — Laboratory and Testing Facility Analysis Procedures: Non-Instrumented Testing

Potential Modification:

Change Section 2.7(f)(1) to specifically prohibit the use of non-instrumented testing devices. The NRC would not allow these devices to be used until HHS has completed its review and provides guidelines. In addition, the NRC would monitor HHS's progress on the matter.

Background:

HHS has been tasked by Congress to review the use of non-instrumented testing devices. As yet, Congress has not provided funds to support this review. HHS is the appropriate regulatory body to deal with this question. Although HHS's progress may be affected by a lack of funding, it has initiated some efforts, as evidenced by the Scientific Meeting on Drug Testing of Alternative Specimens and Technologies it sponsored on April 28-30, 1997. Much useful information was presented at that meeting, and HHS has requested additional information for its consideration.

Many commenters noted the advantages to the industry of using these devices. For example, these devices may prove to be a relatively less expensive and a more convenient means of conducting screening tests, particularly at remote locations. Non-instrumented testing devices are appropriate for validity testing as required by 2.7(e). In congruence with changes to §2.7(e) this section also would be revised to allow use of non-instrumented testing devices for determining specimen validity.

Related Summary Comments: 9.1.1

Effect on Industry:

This change will prohibit the use of these devices in an FFD program that implements 10 CFR Part 26.

Recommendation: Adopt this change.

Rule Reference:

Proposed rule in FR:

2.7 (f) "On-site and Laboratory Screening Tests."

(1) For the analysis of urine specimens, any screening test performed by a licensee's testing facility and the screening test performed by an HHS-certified laboratory must use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The screening test of breath for alcohol performed at the collection site must use a breath measurement device which meets the requirements of Section 2.7 (p) (3) of this appendix. The following initial cut-off levels must be used when screening specimens to determine whether they are negative for the indicated substances:

Recommended modification to proposed rule:

2.7 (f) "On-site and Laboratory Screening Tests."

(1) For the analysis of urine specimens, any screening test performed by a licensee's testing facility and the screening test performed by an HHS-certified laboratory must use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. Pending HHS (SAMSHA) review and approval of non-instrumented immunoassay testing devices, such devices shall not be used to test for drugs of abuse in NRC-regulated FFD programs. Non-instrumented devices may be used for the tests to determine specimen validity required by §2.7(e). The screening test of breath for alcohol performed at the collection site must use a breath measurement device which meets the requirements of § 2.7 (p) (3). The following cut-off levels must be used when screening specimens to determine whether they are negative for the indicated substances:

24. Appendix A, Section 2.7(h)(1) — Laboratory and Testing Facility Analysis Procedures: HHS-Certified Laboratory Reporting Time

Potential Modification:

Do not make the currently proposed change to Section 2.7(h)(1) that would reduce the period within which HHS-certified laboratories must report test results to licensees from five to four working days.

Background:

Several commenters objected to this change because it would create a difference between the NRC and HHS rules for no pressing reason.

Related Summary Comments: 4.2.4; 9.5.2

Effect on Industry: None

Recommendation:

Adopt the commenters' recommendation by deleting the currently proposed change from five days to four days.

Rule Reference:

Proposed rule in FR:

(h) "Reporting Results."

(1) The HHS-certified laboratory shall report test results to the licensee's Medical Review Officer within 4 working days (6 for suspected amphetamines) after receipt of the specimen by the laboratory. Before any test result is reported, the results of screening tests, confirmatory tests, and quality control data, as applicable, must be reviewed and the test certified as an accurate report by the responsible individual at the laboratory. The report must identify the substances tested for, whether positive or negative; the cut-off(s) for each; the specimen number assigned by the licensee; any indications of tampering, adulteration, or dilution that may be present; and the drug testing laboratory specimen identification number.

Recommended modification to proposed rule:

(h) "Reporting Results."

(1) The HHS-certified laboratory shall report test results to the licensee's MRO within 5 working days (6 for suspected amphetamines) after receipt of the specimen by the laboratory. Before any test result is reported, the results of screening tests, confirmatory tests, and quality control data, as applicable, must be reviewed and the test certified as an accurate report by the responsible individual at the laboratory. The report must identify the substances tested for, whether positive or negative; the cut-off(s) for each; the specimen number assigned by the

licensee; any indications of tampering, adulteration, or dilution that may be present; and the drug testing laboratory specimen identification number.

25. Appendix A, Section 2.7(k) — Laboratory and Testing Facility Analysis Procedures: Split Specimens

Potential Modification:

Revise Section 2.7(k) of Appendix A to assure that there is no implication that split specimens are required or that a lack of a split specimen positive result would automatically invalidate an original primary specimen positive result. Further revise this section to require that, when there is a split specimen and that specimen tests negative, the MRO shall consider both test results and other relevant information to determine whether there is a FFD policy violation. Also, make two minor revisions to provide that the split specimen can be sent within the next three business days instead of “that day,” and to make the section consistent with Section 2.4(g)(11) regarding quantity of split specimens. Finally, remove the requirement that licensees provide at least 72 hours for an individual to request that the split specimen be tested.

Background:

Several commenters were concerned that wording in this section could imply that split specimens are required or that the outcome of a test of a split specimen would outweigh a previous positive test result on the primary specimen. The rule does not require licensees to split specimens; it permits them to do so.

Furthermore, the rule does not now imply that a negative test result on a split specimen should override a positive result on the primary specimen. Section 2.9(b) of Appendix A currently permits the MRO to consider the results of tests on split specimens. These sections leave it to the MRO to exercise discretion in determining whether a negative result on a split specimen should negate a positive result on the primary specimen. The HHS Mandatory Guidelines, on the other hand, require the MRO to void the positive test result on the primary specimen in such circumstances.

Additionally, commenters asserted that the requirement that a split specimen be sent “that day” would be impossible to implement in some circumstances. Finally, a commenter noted that the direction to split a specimen in half was no longer consistent with Section 2.4(g)(11), and another objected to the minimum 72-hour period that this section would allow for tested people to request their split specimens to be tested.

Related Summary Comments: 7.6.6; 9.5.4; 9.5.5

Effect on Industry: The proposed changes may avoid unintended problems.

Recommendation:

This section need not be revised to assure that there is no implication that split specimens are required. It currently clearly states that licensees can split specimens at their own option but are not required to do so.

This section should be revised to clearly state that, if a split specimen test result fails to reconfirm the test result on a primary specimen, the MRO should continue to have the

discretion to determine whether or not a FFD policy violation has occurred. Also, new wording should be added to this section that would direct the MRO to consider the conflicting results on the two tests plus any other relevant information in making the FFD policy violation decision. This approach, although different from that in the HHS Mandatory Guidelines where MROs are required to void positive test results on primary specimens in these circumstances, would be consistent with long established NRC philosophy that MROs should be making the determination based upon all relevant information. This approach is recommended because the split specimen can deteriorate over time and may produce a negative result. HHS requires testing at LOD to limit the probability of that happening. Conflicting results on primary and split specimens should occur only very infrequently because confirmation tests of both the primary and split specimens are being conducted by HHS-certified laboratories. If such cases do occur, it is important that the MRO has the discretion to determine the cause of the discrepancy. If the cause is a testing error in either the primary or the split specimen, Section 2.8(f) as proposed to be revised, would require the licensee to investigate and correct any testing errors or other unsatisfactory performance in the testing process.

Four other changes to this section are also recommended. One would remove the specification that the specimen be split in half, since the specimen is now split into two unequal parts. Another would provide three weekdays (not to include holidays) for the split specimen to be forwarded rather than having to be forwarded "that day." Another would remove the requirement that licensees provide at least 72 hours after the individual has been notified for the individual to request that the split specimen be tested. Finally, clarification that the split sample can be tested only at the request of the individual would be made.

Rule Reference:

Proposed rule in FR:

(k) "Split Specimens." Urine specimens may be split, at the licensee's discretion, into two parts at the collection site. One half of such specimens (hereafter called the primary specimen) must be analyzed by the licensee's testing facility or the HHS-certified laboratory for the licensee's purposes as described in this appendix. The other half of the specimen (hereafter called the split specimen) may be withheld from transfer to the laboratory, sealed, and stored in a secure manner by the licensee until all processing of the primary specimen has been completed. If the primary specimen is determined to be negative and free of any evidence of subversion, the split specimen in storage may be destroyed. If the unconfirmed positive result of a screening test has been confirmed, or if the primary specimen is determined to have been subject to adulteration, dilution, or other means of testing subversion, the tested individual may request in a timely manner (as established by the licensee, but not to be restricted to less than 72 hours from the time of the individual's notification of the screening test result) that the split specimen be tested. The individual must be informed of this option. The split specimen must be forwarded on the day of the request to another HHS-certified laboratory that did not test the primary specimen. The chain-of-custody and testing procedures to which the split specimen is subject, must be the same as those used to test the primary specimen and must meet the standards for retesting specimens. I.e., the quantification of the result is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite (Section 2.7 (j) of this appendix). The quantitative results of any second testing process shall be made available to the Medical Review

Officer and to the individual tested. Except as noted in this section, all other requirements of this appendix applicable to primary specimens shall also be applicable to split specimens.

Recommended modification to proposed rule:

(k) "Split Specimens." Urine specimens may be split, at the licensee's discretion, into two parts at the collection site in quantities described in § 2.4(g)(11). One part of samples each specimen (hereafter called the primary specimen) must be analyzed by the licensee's testing facility or the HHS-certified laboratory for the licensee's purposes as described in this appendix. The other part of the specimen (hereafter called the split specimen) may be withheld from transfer to the laboratory, sealed, and stored in a secure manner by the licensee until all processing of the primary specimen has been completed. If the primary specimen is determined to be negative and free of any evidence of subversion, the split specimen in storage may be destroyed. If the presumptive positive screening test result of a primary specimen has been confirmed, or if the primary specimen is determined to have been subject to adulteration, dilution, or other means of testing subversion, the tested individual may request in a timely manner (as established by the licensee) that the split specimen be tested. The individual must be informed of this option, and the split specimen can be tested only at the request of the individual. The split specimen must be forwarded as soon as practicable, but in no case more than three week days (Monday to Friday, not including holidays) following the day of the request to another HHS-certified laboratory that did not test the primary specimen. The chain-of-custody and testing procedures to which the split specimen is subject must be the same as those used to test the primary specimen and must meet the standards for retesting specimens, i.e., the quantitation of the result is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite or substantiate the previous information (paragraph 2.7 (j)). The quantitative results of testing of the split specimen shall be made available to the MRO and to the individual tested. Except as noted in this section, all other requirements of this appendix applicable to primary specimens shall also be applicable to split specimens. If the result of the test of the split specimen fails to reconfirm or substantiate the result reported for the primary specimen, the MRO shall take into account the primary specimen test result, the data regarding presence or absence of drug or metabolite in the split specimen, any evidence of subversion, and any other relevant information to determine whether the test results should be verified as a FFD policy violation. The licensee must investigate, take corrective action as appropriate in response to, and report to the NRC failure to reconfirm as directed in Section 2.8(f) of Appendix A.

26. Appendix A, Section 2.8(e)(3) — Quality Assurance and Quality Control: Controls for Dilute Specimens

Potential Modification:

Remove the Section 2.8(e)(3) requirement for diluting blind performance test specimens and spiking them at 60 percent of the cut-off level. Add language to Section 2.8(c) and (d) regarding quality assurance for blind performance test specimens.

Background:

Commenters argued that the technical requirements for diluting and spiking blind performance test specimens would be too difficult to meet, and that the proposed revision would create more problems than it would solve.

Related Summary Comments: 9.4.1

Effect on Industry: The proposed change removes a requirement, and this decreases burden.

Recommendation:

Do not eliminate the proposed requirement for adulterating or diluting blind performance test specimens and spiking them at 60 percent of the cut-off level. Good quality blind performance test specimens play an essential role in generally assuring that the FFD testing process is reliable and accurate. Requiring that some blind test specimens are diluted or adulterated and spiked will accomplish the specific purpose of assuring that testing laboratories are capable of determining specimen validity, an essential factor in verifying the integrity of the overall testing process. Adulterating or diluting blind performance test specimens and spiking them at 60 percent of the cut-off levels would not be technically difficult. Vendors that formulate blind performance test specimens should be capable of providing specimens to meet this new requirement, and of doing so at a reasonable cost. Presenters at the Scientific Meeting on Drug Testing of Alternative Specimens and Technologies sponsored by HHS on April 28-30, 1997, stated that there are no problems with preparing adulterated or diluted blind performance specimens.

While this new requirement should not be eliminated, it should be modified. Item 20 of this document proposes a new revision to Section 2.7(e) that would require licensees to have their HHS-certified laboratories screen test specimens of questionable validity at the lowest concentration level the laboratories are capable of performing. In light of that proposed revision, the currently proposed spiking requirement in Section 2.8(e)(3) should also be modified to give licensees the flexibility needed to respond to the new revision to Section 2.7(e). Rather than requiring a spiking level at 60 percent of the cut-off level, this proposed change to Section 2.8(e)(3) should be revised to require that the adulterated or diluted blind performance specimens be spiked to between 60 and 80 percent of the licensee's cut-off level. This variable spiking requirement would enable each licensee to tailor its blind performance specimens depending on the lowest screening concentration levels its particular HHS-certified laboratory is capable of performing.

Rule Reference:

Proposed rule in FR:

2.8(e)(3) Approximately 50 percent of the blind performance test specimens must be blank (i.e., certified to contain no drug) and the remaining specimens must be positive for one or more drugs per specimen in a distribution such that all the drugs for which the licensee is testing are included in approximately equal frequencies of challenge. The positive specimens must be spiked only with those drugs for which the licensee is testing. In addition, 10 percent of the positive blind specimens must be appropriately adulterated or diluted and "spiked" to 60 percent of the cut-off value to challenge the laboratory's ability to determine specimen validity, as required by Section 2.7(e) of this appendix.

Recommended modification to proposed rule:

2.8(e)(3) Approximately 50 percent of the blind performance test specimens must be blank (i.e., certified to contain no drug) and the remaining specimens must be positive for one or more drugs per specimen in a distribution so that all the drugs for which the licensee is testing are included in approximately equal frequencies of challenge. The positive specimens must be spiked only with those drugs for which the licensee is testing. In addition, 10 percent of the positive blind specimens must be appropriately adulterated or diluted and spiked to between 60 and 80 percent of the screening cut-off values established by section 2.7(f) of this appendix, or of any lower cut-off values established by the licensee, to challenge the laboratory's ability to determine specimen validity and perform special processing, as required by section 2.7(e) of this appendix.

27. Appendix A, Section 2.9(c) — MRO Verification of Positive Test Results

Potential Modification:

Revise Section 2.9(c) to expand its coverage to all FFD policy violations, to authorize MROs to declare a FFD policy violation when the employee does not report to the MRO after notification to report, and to allow the MRO to rescind a declaration of FFD policy violation if the employee reports to the MRO after being unavailable for an extended period and has a legitimate explanation for the positive test result and failure to report promptly.

Background:

Commenters requested guidance for situations in which employees who have confirmed positive test results leave the employer or, for other reasons, do not report to the MRO for an interview to discuss the test result. Changes to Section 2.9(c) would provide guidance for handling these situations consistent with provisions in the DOT Procedures for Transportation Workplace Drug Testing Programs. These changes would allow the MRO to verify a laboratory confirmed positive test result without having communicated directly with the employee when the person refuses to be interviewed by the MRO, cannot be contacted for 14 days, or does not contact the MRO within 5 days after being contacted by the licensee. Another revision to this section would authorize the MRO, after a documented best-efforts attempt to contact the employee, to declare a laboratory confirmed positive test result to be a FFD policy violation without having interviewed the person. Provisions for overturning this ruling would also be provided. In a related revision, Section 2.9(c) would also be revised to expand its coverage from only positive test results to all FFD policy violations.

Related Summary Comments: 6.3.4

Effect on Industry:

These changes would grant MROs greater flexibility in handling situations involving an inability to verify FFD policy violations. They would probably create no cost differences.

Recommendation: Adopt these changes.

Rule Reference:

Proposed rule in FR:

2.9(c) "MRO Verification of Positive Test Results." Before making a final decision to verify a laboratory confirmed positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result with him or her. Following verification of a laboratory confirmed positive test result as a violation of FFD policy, the Medical Review Officer shall, as provided in the licensee's policy, immediately notify the applicable employee assistance program and the licensee's management official empowered to recommend or take administrative action (or the official's designated agent). Unconfirmed test results must not be reported except as provided by § 26.24(d).

Recommended modification to proposed rule:

2.9(c) "Medical Review Officer verification of FFD policy violations."

(1) Before making a final decision to verify a laboratory confirmed positive test result, or other occurrence that would constitute a FFD policy violation (e.g., attempted subversion), the MRO shall give the individual an opportunity to discuss the test result or other occurrence with him or her. Following verification of a laboratory confirmed positive test result or other occurrence as a violation of FFD policy, the MRO shall, as provided in the licensee's policy, immediately notify the applicable employee assistance program and the licensee's management official empowered to recommend or take administrative action (or the official's designated agent). Presumptive positive screening test results must not be reported except as provided by § 26.24(d).

(2) The MRO may verify a laboratory confirmed positive test result, or otherwise make a determination of FFD policy violation, without having discussed the test result or other occurrence directly with the individual in the following three circumstances:

(i) When the MRO contacts the individual, the individual expressly declines the opportunity to discuss the test result or other occurrence that may constitute a FFD policy violation;

(ii) The MRO, after making all reasonable efforts, has been unable to contact the individual within 14 days of the date on which the MRO receives notice of the laboratory confirmed positive test result, evidence of subversion of the testing process, or other activity that would constitute a FFD policy violation;

(iii) A licensee representative has successfully made and documented contact with the individual and instructed him or her to contact the MRO and more than five days have passed since the date the individual was successfully contacted by the licensee representative.

(3) If the MRO makes a determination of a FFD policy violation under the circumstances specified in § 2.9 (c) (2) (ii) or (iii), the individual may present to the MRO information documenting that serious illness, injury, or other circumstances unavoidably prevented him or her from being contacted by the MRO or licensee representative or from contacting the MRO in a timely manner. The MRO, on the basis of this information, may reopen the procedure for determination of a FFD policy violation and allow the individual to present information relating to the issue. The MRO may modify the initial determination based on an evaluation of the information provided.

28. Appendix A, Section 2.9(d) — Reporting and Review of Results: Clinical Evidence

Potential Modification:

Remove language from Section 2.9(d) of Appendix A that includes evidence of lack of reliability and trustworthiness as “clinical evidence” of opiate abuse and add admission of non-prescribed opiate use as an example of such evidence.

Background:

Commenters requested guidance and argued convincingly that equating lack of reliability and trustworthiness to "clinical evidence" would not be a practical approach for verifying opiate abuse. It is understandable that lack of reliability or trustworthiness would be a concept that licensees could find difficult to use in a practical way. Nonetheless, two other minor additions to this Section would serve to expand the types of clinical evidence that MROs can use to verify opiate positive test results. First, the staff is aware that some licensees have interpreted the examples of clinical evidence of abuse set forth in this section to be all inclusive. To make it clear that the examples of clinical signs of opiate abuse listed in this section are not to be the only types of evidence to be used to verify a laboratory confirmed positive test result, the words "but not limited to" should be added to this section. This should make it clear that MROs are to consider other types of clinical evidence beyond those listed in this section. The second change would be to add "admission of non-prescribed opiate use" to the list of examples. This change would respond to questions from licensee FFD program staff as to whether such admissions are to be considered clinical evidence of opiate abuse.

Related Summary Comments: 15.3.1

Effect on Industry: There would be no impact on the industry.

Recommendation: Adopt these changes.

Rule Reference:

Proposed rule in FR:

(d) "Verification for opiates." Before the Medical Review Officer verifies a laboratory confirmed positive result as a violation of FFD policy and the licensee takes action for opiates, he or she shall determine that there is reasonable and substantial clinical evidence--in addition to the urine test--of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). Clinical evidence may include substantial evidence of a significant lack of reliability or trustworthiness on the part of the worker. Clinical signs of abuse include recent needle tracks or test results that are inconsistent with the ingestion of food or medication including prescription medications containing opiates (e.g., 6-AM test); clinical signs of abuse also include behavioral and psychological signs of acute opiate intoxication or withdrawal. This requirement does not apply if the GC/MS confirmation testing for opiates confirms the presence of 6-acetylmorphine.

Recommended modification to proposed rule:

(d) "Verification for opiates." Before the Medical Review Officer verifies a laboratory confirmed positive result as a violation of FFD policy and the licensee takes action for opiates, he or she shall determine that there is reasonable and substantial clinical evidence--in addition to the urine test--of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). Clinical signs of abuse include recent needle tracks or test results that are inconsistent with the ingestion of food or medication including prescription medications containing opiates (e.g., 6-AM test); clinical signs of abuse also include, but are not limited to, behavioral and psychological signs of acute opiate intoxication or withdrawal, or admission of non-prescribed opiate use. This requirement does not apply if the GC/MS confirmation testing for opiates confirms the presence of 6-AM since the presence of this metabolite is proof of heroin use.

APPENDIX A

TO ATTACHMENT C

**LISTING OF POTENTIAL MODIFICATIONS TO PROPOSED REVISIONS TO 10 CFR
PART 26 THAT ARE
NOT RECOMMENDED**

A.1 Section 26.3 — Definitions: Congruence with HHS

Potential Modification:

Various definitions in Section 26.3 would be revised to match HHS definitions for the same terms.

Background:

Commenters believe that consistent definitions among federal programs would make things easier for everyone. When the staff came up with NRC's new terms, HHS had not finalized its new mandatory guidelines. Some of the terms in the original HHS guidelines were aimed at laboratory personnel and were confusing and/or misleading to FFD program managers. Most of the existing differences between NRC and HHS definitions were deliberately made because of differences in the programs: NRC permits testing at lower concentration levels and for additional drugs, and requires testing for alcohol. A preliminary comparison of all federal definitions indicates no important differences. See table below for a comparison of HHS and NRC definitions.

Related Summary Comments: 6.3.1; 6.5.1; 6.5.2

Effect on Industry: There would probably be no impact on the industry.

Recommendation:

No changes especially related to HHS definitions. Some other definitional changes may respond in part to this potential rule change.

Rule Reference:

Proposed rule:

Not applicable.

A.2 Section 26.3 — Definitions: Confirmation Test

Potential Modification:

Clarify the current definition of a confirmation test in regard to alcohol testing to read “A confirmation test would be the second test, following a test with a result of 0.02 percent or greater that provides quantitative data of alcohol concentration.” A similar revision to Section 2.4(g) of Appendix A is also suggested.

Background:

A commenter recommends this change in order to increase clarity and consistency with the 0.02 percent BAC changes and to remove requirements for a second confirmatory process. However, the “quantitative data” addition is not necessary because the type of testing devices specified in Section 2.7(p)(3) of Appendix A provides quantitative data. The cut-off levels for all drugs and for alcohol are in Sections 2.7(f) and (g) of Appendix A, not in the definitions. In addition, the change proposed by the commenter might create confusion regarding the requirements for initial and confirmatory alcohol tests, both of which are necessary.

Related Summary Comments: 6.3.2; 6.3.3

Effect on Industry: There would be no impact on the industry.

Recommendation:

The Section 26.3 definition should not be revised, because the current definition is sufficiently clear. The commenter's recommendation that this definition mention the 0.02 percent BAC cut-off level should not be adopted. Cut-off levels are stated in Appendix A, not in the definitions. The NRC should continue to require a second set of tests on a second device as the confirmatory test.

Rule Reference:

Proposed rule:

Confirmatory test means a second analytical procedure to identify the presence of a specific drug or drug metabolite which is independent of the screening test and which uses a different technique and chemical principle from that of the screening test in order to ensure reliability and accuracy. (At this time, gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.) For determining blood alcohol levels, a "confirmatory test" means a second test using another breath alcohol analysis device. Additional information may be obtained by gas chromatography analysis of blood.

A.3 Section 26.3 — Definitions: Medical Determination of Fitness

Potential Modification:

This change would revise the definition of “medical determination of fitness” to allow licensees to use other appropriately certified medical professionals (probably registered nurses or licensed practitioners with specialty training) to perform a medical determination of fitness.

Background:

Some commenters felt that continuing to restrict medical determinations of fitness to a licensed physician is unnecessary and creates problems of availability of a licensed physician/MRO during off peak hours. This indicates that some licensees may be more interested in maintaining scheduled staffing (i.e., returning people to work as soon as possible) than in assuring that safety is maintained by assuring there is no unresolved impairment concern. The NRC continues to believe that considerations of safety and program integrity require that licensed physicians continue to make these determinations.

Related Summary Comments: 6.2.2; 15.1.3

Effect on Industry: No impact.

Recommendation: This definition should not be revised.

Rule Reference:

Proposed rule:

Medical determination of fitness means the process whereby a licensed physician, who may be the MRO, qualified to make such determination examines and interviews an individual and reviews any appropriate and relevant medical records, in accordance with standard clinical procedures, in order to determine whether there are indications that the individual may be in violation of the licensee’s FFD policy or is otherwise unable to safely and competently perform duties. The qualifications for making the determination are related to the fitness issues presented by the patient.

A.4 Section 26.3 — Definitions: Supervisor

Potential Modification:

Revise definition of "supervisor."

Background:

A commenter suggested that the definition should make clear that the supervisor should apply behavioral observation to all personnel, not only those for whom the supervisor has immediate oversight responsibilities. The definition simply defines the supervisor as someone who directs activities of others without establishing FFD responsibilities. Although licensees may want their supervisors to observe everyone, for impairment (long term performance trends would not be practical), the NRC staff believes it is not something the NRC should mandate by regulation. Licensees may encourage such practices and may want to put this idea in their FFD policies and procedures. A minor edit, adding the words "or control" is proposed.

Related Summary Comments: 6.4.2

Effect on Industry: None.

Recommendation: Do not adopt the change.

Rule Reference:

Proposed Rule:

Supervisor means any person who has the immediate oversight responsibilities to direct or control activities of any other person or persons within the protected area or has ongoing responsibility for the supervision of an individual with unescorted access status while that individual is not in the protected area.

A.5 Section 26.24 — Chemical Testing: Skipping Screening Test

Potential Modification:

Revise Sections 26.24(d)(1) and (g) and Sections 2.7 (d) and (f) to provide that specimens screened positive on site are tested by GC/MS without a HHS-certified laboratory screening test.

Background:

This change was proposed by a commenter to reduce false negatives. Section 26.24 (f) requires that all specimens sent to HHS-certified laboratories be subject to a screening test unless the specimen is suspect. HHS has emphasized a number of times the importance of the screening test to GC/MS confirmation testing (i.e., determining dilution ratios). Suspect (adulterated or dilute) specimens would be submitted for special processing. The current rule allows licensees to have all specimens tested at more stringent cutoff levels for both screening and GC/MS testing. Using lower screening cutoff levels at the HHS-certified laboratory should overcome most problems with false negatives.

Related Summary Comments: 9.2.2

Effect on Industry:

This would only affect licensees that test on site. It would create an additional burden in that these licensees would be required to do GC/MS testing on all of the specimens that they send to the laboratory.

Note: Section 2.8(b) of Appendix A requires a sampling of negatives from every test run conducted on site to be submitted to the HHS certified laboratory. To prevent compromise of the testing process, all specimens submitted to the HHS certified lab must be treated the same (except where adulteration or dilution are suspected).

Recommendation:

Don't change the rule to require GC/MS testing of on-site screening positive test results without a screening test by the laboratory. Provide a discussion of the current flexibility in the rule in the statement of considerations.

Rule Reference:

Proposed rule:

(d) (1) All collected urine and blood specimens must be forwarded to a laboratory certified by the Department of Health and Human Services (HHS), except that licensees may conduct tests of aliquots to determine which specimens are negative and need no further testing, provided the licensee's staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for the testing are implemented. All such testing of specimens must include tests to ensure specimen validity as required by Section 2.7 (e) of Appendix A to Part 26. Quality control procedures for screening tests by a licensee's

testing facility must include the processing of blind performance test specimens and the submission to the HHS-certified laboratory of a sampling of specimens initially analyzed as negative. Except for the purposes discussed in § 26.24 (d) (2), access to the results of the above screening tests must be limited to the licensee's testing staff, the Medical Review Officer (MRO), the Fitness-for-Duty Program Manager, and employee assistance program staff, when appropriate.

(g) All testing of urine specimens for drugs, except screening tests performed by licensees under paragraph (d) of this section, must be performed in a laboratory certified by HHS for that purpose consistent with its standards and procedures for certification. Except for suspect specimens submitted for special processing (§ 2.7 (d) or (e) of Appendix A to part 26), all specimens sent to HHS-certified laboratories must be subject to screening analysis by the laboratory and all specimens screened as presumptive positives must be subject to confirmatory testing by gas chromatography/mass spectroscopy analysis by the laboratory. Licensees shall submit blind performance test specimens to HHS-certified laboratories in accordance with the NRC Guidelines (Appendix A). Licensees must ensure that all collected specimens are tested and that laboratories report results for all specimens sent for testing, including blind performance test specimens.

A.6 Section 26.24 — Chemical Testing: Blood Test for Alcohol

Potential Modification:

Sections 26.24(h) and 2.4(g)(19) would be revised to remove the requirement that licensees allow individuals to request a blood test for alcohol after a confirmed alcohol positive test.

Background:

Some commenters believe the blood test for alcohol doesn't add any meaningful information and it is expensive and difficult to make it available at all times. NRC Office of General Counsel and some commenters favor the blood test option because it provides a means of appeal for employees and makes alcohol test results more defensible in court.

Related Summary Comments: 10.3.1

Effect on Industry:

If this change was made the industry's costs would be reduced due to not having to maintain ready access to personnel qualified to draw blood and collection apparatus nor pay for blood tests.

Recommendation:

Do not adopt the change. Make minor edits as noted, including specifying "whole" blood.

Rule Reference:

Proposed rule:

26.24(h) Tests for alcohol must be administered by breath analysis using breath alcohol analyses devices meeting evidential standards described in Section 2.7 (p)(3) of Appendix A to Part 26. If the screening test shows a breath alcohol content indicating a BAC of 0.02 percent or greater, a confirmatory test for alcohol must be performed using another breath measurement instrument. A confirmatory test result showing a breath alcohol content indicating a BAC between 0.02 percent and 0.04 percent must be forwarded to the MRO for evaluating as described in Section 2.9 (h) of Appendix A to Part 26. A confirmatory test for alcohol indicating a blood alcohol concentration (BAC) of 0.04 percent or greater must be declared a positive test. Further testing for alcohol must be administered if demanded by the individual for the purposes of obtaining additional information that could be considered during an appeal pursuant to §26.28. Any such test must be a gas chromatography analysis of whole blood performed on a blood specimen drawn, with the consent of the individual, promptly after the confirmatory breath analysis. Any detectable quantity of alcohol in the blood specimen may be considered, including extrapolation back in time, to determine if a violation of the FFD policy occurred.

2.4 (g) (19) If the alcohol breath tests indicate that the individual is positive for a BAC at or above the 0.04 percent cut-off level or that the individual may have been positive for a BAC at or above the 0.04 percent cut-off level during any scheduled working tour (i.e., has a confirmatory

test result between 0.02 percent BAC and 0.04 percent BAC), the individual may request a blood test, at his or her discretion, for the purpose of obtaining additional information that could be considered during an appeal. The blood specimen should be drawn immediately, if possible. All vacuum tube and needle assemblies used for blood collection must be factory-sterilized. The collection site person shall ensure that they remain properly sealed until use. Antiseptic swabbing of the skin must be performed with a nonethanol antiseptic. Sterile procedures must be followed when drawing blood and transferring the blood to a storage container; in addition, the container must be sterile and sealed.

A.7 Section 26.24(a)(1) — Chemical Testing: Access Prior to Preaccess Negative Test Result

Potential Modification:

Currently proposed changes to the preaccess testing requirements in Section 26.24(a)(1) would be modified in three ways. The first modification would eliminate the proposed change that would allow licensees to forgo preaccess testing of employees who have recently been covered by a program meeting Part 26 standards. The second modification would eliminate the proposed change that would allow licensees to grant immediate unescorted access to employees who have been covered by a program meeting Part 26 standards for two consecutive weeks in the past 60 days. These two modifications would provide licensees with less flexibility to eliminate unneeded preaccess testing and to grant access before negative test results have been obtained.

The third modification would consist of an editorial replacement of "no history indicating the use of illegal drugs or the abuse of legal drugs (e.g., alcohol, prescription, and over-the-counter drugs)" with "no history of substance abuse."

Background:

A number of commenters noted that the NRC's proposed conditions under which preaccess testing is not necessary and when access could be granted before negative test results are obtained would be difficult to understand and track. The tracking system currently available to licensees notes when a negative test result was received but not the length of time an individual was covered by a program.

Related Summary Comments: 7.1.1; 7.1.3; 7.1.4; 7.1.9; 7.1.10

Effect on Industry:

This change would make the revision easier for industry to understand but would reduce the number of workers affected. Therefore, it would reduce the amount of money the industry could save. The implementation of the proposed revision is optional.

Recommendation:

The currently proposed changes to Section 26.24(a)(1) should not be modified as the commenters proposed. These changes as originally proposed would produce program efficiencies in that some unnecessary preaccess testing would be eliminated and some workers who have demonstrated reliability could gain immediate access rather than having to wait for negative test results. If licensees are unable to take advantage of these efficiencies at this time because the industry's data base does not contain the necessary information, licensees can continue to conduct preaccess testing according to the same procedures it has used for the past several years. These rule relaxations should be put in place now to provide the benefits where they can be realized and to accommodate any action by the industry should it wish to revise the data it collects regarding workers' employment periods so as to be able to achieve these program efficiencies on a broader scale.

The third change mentioned above should be made. This minor administrative change would be made in conjunction with another change that would add a new definition of "history of substance abuse" to Section 26.3.

Rule Reference:

Proposed rule:

(a) To provide a means to deter and detect substance abuse, the licensee shall implement the following chemical testing programs for persons subject to this part:

(1) (i) Preaccess testing for drugs and alcohol must be conducted within 60 days before the granting of unescorted access to protected areas or assignment to activities within the scope of this part unless the individual:

(A) Has been covered by a program meeting the requirements of this part for at least 30 days during the 60 days immediately previous to the granting of unescorted access, and

(B) Has no history of substance abuse.

(ii) Any negative drug and alcohol test meeting the standards of this part and performed within 60 days before granting unescorted access may serve as the preaccess test. A negative test result must be obtained before the granting of unescorted access unless the individual has no history of substance abuse and has either had a negative test result on a test meeting the standards of this part performed within six months before granting unescorted access or has been covered by a program meeting the standards of this part for two consecutive weeks during that period.

A.8 Section 26.24(a)(5) — Chemical Testing: Access Prior to Negative Return-to-Duty Test Results

Potential Modification:

Change Section 26.24(a)(5) to reduce the options for granting unescorted access prior to obtaining a negative test result for workers returning to duty (return-to-duty testing). This change would make the options similar to those regarding waiting for negative test results under pre-access testing. In addition, make a minor edit to this section.

Background:

The flexibility to grant access before obtaining negative results would be more limited, but also less confusing.

Related Summary Comments: 7.5.1; 7.5.3; 7.5.5

Effect on industry:

This change would reduce the number of workers affected and, hence, reduce the amount of money the industry could save.

Recommendation:

This change should not be adopted, however, the minor administrative edit should be made. As originally proposed, the changes to this section would allow return-to-duty testing to be conducted more efficiently. While most licensees may not be able to take advantage of these changes at this time due to lack of information, these changes may encourage the industry to improve its information gathering to ultimately be able to take advantage of these changes. This section should be modified as indicated to recognize the new definition of "history of substance abuse."

Rule Reference:

Proposed rule:

(5) Return-to-duty testing must be conducted when a person seeks to regain unescorted access to protected areas of the site in question after an absence from the possibility of being tested under that site licensee's program for more than 60 days or when a person seeks to regain unescorted access after having been denied access under the provisions of § 26.27(b). Any negative drug and alcohol test meeting the standards of this part and performed within 60 days before the granting of unescorted access may serve as the return-to-duty test except in the case of those who have been denied access under the provisions of § 26.27(b). A negative test result must be obtained before the granting of unescorted access unless the individual has no history of substance abuse and either has had a negative test result on a test meeting the standards of this part performed within six months before the reinstatement of unescorted access or has been covered by a program meeting the standards of this part for two consecutive weeks during that period.

A.9 Section 26.24(f) — MRO Unable to Interview Employee

Potential Modification:

Revise Section 26.24(f) to allow licensees to temporarily restrict the unescorted access of employees who have a laboratory confirmed positive test result but do not report promptly to the MRO for an evaluation.

Background:

Commenters requested guidance for handling situations in which an employee having a laboratory confirmed positive test result does not report to the MRO for an interview or cannot be contacted. These commenters considered it inappropriate for an employee to continue to have unescorted access while waiting to be interviewed by the MRO. The commenters recommended that, in such situations, the employee be removed from duty at least until the MRO interview.

Related Summary Comments: 7.7.2, 12.1.1

Effect on Industry: This change would have little or no effect on the industry.

Recommendation:

Do not adopt this change. Section 26.27(b)(1) has always provided licensees with the authority to remove an employee from Part 26 duties if his or her fitness is questionable. In cases where an employee has a confirmed positive test and the employee appears to be unwilling to report for an interview, the MRO can use this authority to temporarily remove the person from Part 26 duties. In addition, Section 2.9(c) has been revised to clarify actions to be taken by the MRO when an individual does not promptly report for an interview.

Rule Reference:

Proposed rule:

(f) The MRO shall complete the review of test results reported by the HHS-certified laboratory and notify licensee management as soon as practicable. The MRO shall report all determinations of violations of the licensee's FFD policy to management in writing and in a manner designed to ensure confidentiality of the information. To assure that action is taken immediately, provisions must be made to ensure that the MRO is able to contact appropriate licensee management at any time. Should the MRO's review not be completed within 14 days of the collection of a specimen, licensee management must be advised of available test results, the status of the review, the reasons for the delay, and appropriate recommendations.

A.10 Section 26.27 — Management Actions and Sanctions: FFD Personnel Sanctions

Potential Modification:

Add language to Section 26.27(b)(1), (3), (4), or (5) to specify what the sanctions would be for FFD personnel in violation of 10 CFR Part 26.

Background:

According to some commenters, the current sanctions do not fit the case of FFD personnel who violate licensee FFD policy. However, this change should not be necessary because Section 26.27(b)(1) specifies that those in violation are to be “removed from activities under the scope of this part” which should now include FFD program activities as specified in Section 26.2. This means that FFD program personnel would be subject to the same requirements relative to being able to resume activities subject to Part 26 as are other employees covered by the rule.

Related Summary Comments: 12.2.1

Effect on Industry: There would be no impact on the industry.

Recommendation: Do not adopt this change. Make minor edits as noted.

Rule Reference:

Proposed rule:

(b) Each licensee subject to this part shall, at a minimum, take the following actions. The requirements of this paragraph do not prohibit the licensee from taking more stringent action.

(1) Personnel, including applicants, who are impaired, those whose fitness may be questionable, and those determined to have violated the licensee's fitness-for-duty policy shall be immediately denied unescorted access or otherwise removed from activities with the scope of this part. These persons may be assigned to or returned to their duties only after impairing or questionable conditions are resolved and the individual is determined to be fit to safely and competently perform activities within the scope of this part by an appropriate manager and a licensed physician qualified to make the medical determination of fitness.

* * * * *

(3) The first violation of the FFD policy involving a confirmed positive drug or alcohol determination must, at a minimum, result in immediate removal from activities within the scope of this part for at least 14 days and referral to the EAP for assessment and counseling during any suspension period. Plans for treatment, follow-up, and future employment, if applicable, must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period. Although the individual must be removed from activities covered by this part if the individual is retained by the licensee in an employment status pending reinstatement of unescorted access, the individual must continue to be covered during any suspension period by

the applicable FFD program with respect to behavioral observation if in a work status, chemical testing, and sanctions for violations of the licensee's FFD policy. Before an individual is permitted to be returned to duty or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform such activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24 (a) (5) must be conducted before the individual may be returned to duty and follow-up testing under § 26.24 (a) (4) must be conducted to verify continued abstinence from the use of substances. Any subsequent violation of FFD policy, including during an assessment or treatment period, must immediately result in revocation of authorization to perform activities described in §26.2(a) for a minimum of 3 years from the date of removal.

(4) Any individual determined to have been involved in the sale, use, or possession of illegal drugs or the use of alcohol while, as applicable, within a protected area of any nuclear power plant, within a facility that is licensed to possess or use SSNM, or within a transporter's facility or vehicle, must immediately have his or her authorization to perform activities within the scope of this part as described in § 26.2 (a) revoked for a minimum of 5 years from the date of revocation.

(5) Persons removed for periods of three years or more under the provisions of paragraphs (b) (2), (b) (3), (b) (4) and (c) of this section and who would have been removed under the current standards of a hiring licensee, may be granted unescorted access and assigned duties within the scope of this part by a licensee subject to this part only when the hiring licensee receives satisfactory medical assurance that the person has abstained from the use of illegal drugs and the abuse of legal drugs for at least three years. Before an individual is permitted to be returned or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform these activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24 (a) (5) must be conducted before the individual may be assigned duties and follow-up testing under § 26.24 (a) (4) must be conducted to verify continued abstinence from the abuse of substances. Any further violation of FFD policy must immediately result in permanent denial from activities described in § 26.2 (a).

A.11 Sections 26.27(b)(3), (4), (5), and (6) — Sanctions for Alcohol Abuse

Potential Modification:

Change Sections 26.27(b)(3), (4), (5), and (6) to remove revisions proposed in 1996 that would explicitly require that sanctions for alcohol abuse be the same as for the use of illegal drugs. Allow licensees to set their own alcohol sanctions as long as those sanctions are sufficient to deter violations with regard to alcohol.

Background:

It has always been the Commission's intention that licensees have sanctions for alcohol abuse that would adequately deter such abuse. The rule revision proposed in 1996 was based on the Commission staff's view that some licensees had adopted sanctions that did not provide sufficient deterrence. As discussed in Chapters 3 and 7 of NUREG/CR-6470, alcohol represents one of the most serious problems in workplace impairment and problems with alcohol abuse by workers are as difficult to address and resolve as those created by illegal drug abuse.

Several commenters objected to equating the sanctions for alcohol and prescription and over-the-counter drug violations with those for the use of illegal drugs. (Note: the proposed rule revisions did not include specified sanctions for prescription and over-the-counter drugs.) Commenters cited as rationales the differences in legality of use, the need for re-education rather than sanctions for alcohol abuse, and that HHS and DOT do not dictate sanctions for first violations regarding alcohol and legal drugs. One commenter agreed with the NRC's logic regarding the importance of alcohol sanctions in a fitness-for-duty program, but argued that, from an employer-policy perspective, there are strong incentives for maintaining a distinction between illegal drugs and alcohol.

Related Summary Comments: 10.3.3; 12.2.3.

Effect on Industry:

This would remove a change that is anticipated to have no cost impact but that would assist licensees in negotiating about and defending sanction decisions with regard to alcohol.

Recommendation:

Do not change these sections to remove the revisions regarding sanctions for alcohol violations that were proposed in 1996. A prescriptive requirement for sanctions as proposed in 1996 would unnecessarily limit the options of the majority of licensees who properly consider positive alcohol tests as a serious FFD violation and take appropriate action against the tested individual. The staff should instead monitor licensees to determine whether they are taking appropriate action against individuals who test positive for alcohol and take appropriate regulatory action if needed.

Rule Reference:

Proposed rule:

(3) The first violation of the FFD policy involving a confirmed positive drug or alcohol determination must, at a minimum, result in immediate removal from activities within the scope of this part for at least 14 days and referral to the EAP for assessment and counseling during any suspension period. Plans for treatment, follow-up, and future employment, if applicable, must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period. Although the individual must be removed from activities covered by this part, the individual must continue to be covered during any suspension period by the licensee's FFD program with respect to behavioral observation if in a work status, chemical testing, and sanctions for violations of the licensee's FFD policy. Before an individual is permitted to be returned to duty or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform such activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24 (a) (5) must be conducted before the individual may be returned to duty and follow-up testing under § 26.24 (a) (4) must be conducted to verify continued abstinence from the use of substances. Any subsequent violation of FFD policy, including during an assessment or treatment period, must immediately result in removal from activities described in § 26.2 (a) for a minimum of 3 years from the date of removal.

(4) Any individual determined to have been involved in the sale, use, or possession of illegal drugs or the use of alcohol while, as applicable, within a protected area of any nuclear power plant, within a facility that is licensed to possess or use SSNM, or within a transporter's facility or vehicle, must immediately be removed from activities within the scope of this part as described in § 26.2 (a) for a minimum of 5 years from the date of removal.

(5) Persons removed for periods of three years or more under the provisions of paragraphs (b) (2), (3), and (4) of this section and who would have been removed under the current standards of a hiring licensee, may be granted unescorted access and assigned duties within the scope of this part by a licensee subject to this part only when the hiring licensee receives satisfactory medical assurance that the person has abstained from the use of illegal drugs or the abuse of legal drugs (e.g., alcohol, prescription and over-the-counter drugs) for at least three years. Before an individual is permitted to be returned or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform these activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24 (a) (5) must be conducted before the individual may be assigned duties and follow-up testing under § 26.24 (a) (4) must be conducted to verify continued abstinence from the use of substances. Any further violation of FFD policy must immediately result in permanent denial from activities described in § 26.2 (a).

(6) Paragraphs (b) (2), (3), (4), and (5) of this section do not apply to valid prescriptions or over-the-counter drugs. Licensee sanctions for confirmed abuse of valid prescription and over-the-counter drugs must be sufficient to deter abuse of legally obtainable substances as a substitute for abuse of proscribed drugs.

A.12 Section 26.71(d) — Program Performance Reports: Combining Contractors

Potential Modification:

Combine short-term and long-term contractors in the program performance summary report required by Section 26.71(d).

Background:

The distinction between short-term and long-term contractors is no longer meaningful because very few licensees are reporting these separately. Instead, in most cases all contractors are reported in the “short-term” category because of the directive on the NUMARC form. The rule does not specify that reporting should be provided separately for short- and long-term contractors. The rule requires reporting “by population tested.”

Related Summary Comments: 17.2.7

Effect on Industry: No impact.

Recommendation:

Take no action to revise the rule. Discuss changes to NEI's standard reporting form with NEI. Make a minor change to allow reporting either annually or semi-annually.

Rule Reference:

Proposed rule:

(d) Collect and compile fitness-for-duty program performance data on a standard form and submit these data to the Commission either for a calendar year period (January 1st through December 31st) or a six month period (January through June, and July through December) by no more than 60 days at the end of the reporting period. The data for each site (corporate and other support staff locations may be separately consolidated) must include: random testing rate; drugs tested for and cut-off levels, including results of tests using lower cut-off levels and tests for other drugs; workforce populations tested; numbers of tests and results by population, and type of test (i.e., pre-access, random, for-cause, etc.); substances identified; summary of management actions; number of subversion attempts by type; and a list of events reported. The data must be analyzed and appropriate actions taken to correct program weaknesses. The data and analysis must be retained for three years. Any licensee choosing to temporarily suspend individuals under the provisions of § 26.24 (d) shall report test results by process stage (i.e., onsite screening, laboratory screening, confirmatory tests, and MRO determinations) and the number of temporary suspensions or other administrative actions taken against individuals based on onsite presumptive positive screening test results for marijuana (THC) and for cocaine.

A.13 Sections 26.71 and 26.73 — Recordkeeping Requirements and Reporting Requirements: OMB Response

Potential Modification:

Make changes to Sections 26.71(d) and 26.73(a)(2) regarding information collection and reporting requirements based on OMB's response to record keeping information request from the NRC.

Background:

OMB has not objected to any current or proposed recordkeeping or reporting requirements.

Related Summary Comment: 17.1.1; 17.2.8; 17.2.13

Effect on industry: No change.

Recommendation: No changes to proposed requirements.

Rule Reference: Not applicable.

A.14 Section 26.73 — Reporting Requirements: Significant Events

Potential Modification:

Add language to clarify requirements under Section 26.73(a) regarding the definition of significant events that must be reported to the NRC.

Background:

Commenter requests this clarification, which would specify all significant FFD events.

Related Summary Comments: 17.2.2

Effect on Industry: There would be no impact on licensees currently in compliance.

Recommendation:

This section should not be modified to further elaborate on what types of events should be considered reportable as significant events. Under its currently proposed revisions, the NRC would add the phrase "but not limited to" to this section. This revision would emphasize that licensees should not consider the examples cited in this section to be all inclusive but should instead respond to the performance expectations of this section. Further listing of reportable significant events could be counter productive in that doing so might tend to give some licensees the impression that only those events listed in this section are reportable.

Rule Reference:

Proposed rule:

(a) Each licensee subject to this part shall inform the Commission of significant fitness-for-duty events including, but not limited to:

(1) Sale, distribution, use, possession, or presence of illegal drugs or use or presence of alcohol within the protected area,

(2) Any acts by any person licensed under 10 CFR Part 55 to operate a power reactor, by any supervisory personnel assigned to perform duties within the scope of this part, or by any FFD program personnel as specified in § 26.2 (a) (4)--

(i) Involving the sale, use, or possession of a controlled substance,

(ii) Resulting in determinations that such an individual has violated the licensee's FFD policy,

(iii) Involving use of alcohol within the protected area, or

(iv) Resulting in a determination of unfitness for scheduled work due to the consumption of alcohol.

(3) Any act that would cast doubt on the integrity of the FFD program, including but not limited to, acts that cast doubt on the honesty and integrity of the FFD program personnel specified in § 26.2 (a) (4),

(4) Arrest of a worker for sale, distribution, use, or possession of illegal drugs on or off site.

(c) No change.

(d) No change.

A.15 Section 2.4 — Specimen Collection Procedures: Temperature

Potential Modification:

Change Section 2.4(g)(13) to include the following revisions: 1) change the temperature range proposed and 2) add language to assure that collectors consider the ambient temperature, etc. There are five options regarding the temperature range: 1) use the currently proposed range, 2) change the temperature range to provide a broader range than proposed but a narrower range than HHS, 3) change the temperature range to agree with HHS and DOT, 4) establish parameters that would reduce the potential for specimens to cool prior to measuring the temperature, or 5) continue to use the temperature range in the current rule (i.e., 32.5°-37.7 °C/90.5°-99.8°F). A discussion of the effects of ambient temperature, etc., is currently contained in the SOC and could be summarized in the rule itself.

Background:

- 1) The argument for a narrower temperature range is that it is a relatively inexpensive and effective means of reducing the potential for subversion of the program through substitution and some dilution. Reducing the temperature range is intended to detect and deter subversion (e.g., through provision of a surrogate sample). Some licensees are already using a narrower temperature range (as allowed by the rule) and find it is successful.
- 2) Many commenters thought that it would be difficult to maintain the narrower range and that this would create problems due to more specimens being “out of range” and requiring follow-up. In related comments there is a position taken that there are many factors, such as time from collection to temperature taking and ambient temperature, that could affect the temperature of the specimen and that these should be taken into account.
- 3) Finally, some commenters want the rule to be the same as HHS and DOT so that the same standards are applied. The argument against this is that there is pretty good evidence that the HHS and DOT temperature ranges are not very effective in detecting subversion.

Related Summary Comments: 11.3.1; 11.3.2; 11.3.3; 11.3.4

Effect on Industry: The change would have a minimal impact on the industry.

Recommendation:

Continue to use the temperature range in the current rule. Upon reconsideration, the Commission has decided not to adopt a narrower temperature range. Insufficient data exists showing whether there would be a significant number of true positives identified using the more restricted temperature range that are currently classified as negatives. Thus, it is unclear whether the benefits of identifying these true positives outweighs the cost of additional confirmatory testing for eliminating false positives.

Rule Reference:

Proposed rule in FR:

(g)(13) Immediately after the urine specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The licensee shall establish the temperature range within which the specimen temperature must fall based on site specific factors that influence the results, to include the type of temperature measuring devices used, the ambient temperature, time from urination to completion of the temperature measurement, and other factors. The licensee shall clearly specify the temperature range and the factors that were the basis for the range in its collection procedures. The temperature range of an acceptable urine specimen must be within a band of 3°C/6°F or less, with a lower limit not lower than 34°C/94°F. The time from urination to temperature measurement must in no case exceed 4 minutes.

Recommended modification to proposed rule:

(g)(13) Immediately after the urine specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement must in no case exceed 4 minutes, and may need to be less because of the ambient temperature.

(g)(14) If the temperature of a urine specimen is outside the range of 32.5°-37.7°C/90.5°-99.8°F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of gender collection site person. Both specimens shall be forwarded to the laboratory for testing. Immediately after a urine specimen is collected, the collection site person shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. Any unusual findings must be noted on the custody-and-control form.

A.16 Section 2.4 — Specimen Collection Procedures: Agreement to Test Under Observation

Potential Modification:

Change Section 2.4(g)(24) so that the MRO or other designated medical professional are not among those who can make decisions regarding obtaining urine specimens under observation.

Background:

The commenter stresses that most requirements for observed testing are not medical but are procedural except in “shy bladder” cases. In fact, the revised rule states that a medical professional OR management shall make this decision. Thus, it would be totally within licensee discretion whether MROs or other medical professionals should be involved in these decisions.

Related Summary Comments: 15.1.9

Effect on Industry: The change would have no effect on the industry.

Recommendation:

Leave the section as is. Licensees should have the option to use MROs or other medical professionals to agree to these decisions. The proposed change added flexibility by allowing either a medical professional or management to make this decision when appropriate.

Rule Reference:

Proposed rule:

(g)(24) Agreement of the MRO, other designated medical professional, or a higher level supervisor of the collection site person, must be obtained in advance of each decision to obtain a urine specimen under direct observation as specified in Section 2.4 (g) (15).

A.17 Section 2.7 — Laboratory and Testing Facility Analysis Procedures: Opiate Cut-Off Levels

Potential Modification:

Change Sections 2.7(f)(1) and 2.7(g)(2) and (5) to raise the opiate cutoff levels and revise the requirements for 6-AM screening as proposed by HHS and discussed in the Statement of Considerations.

Background:

This change is intended to assure consistency with HHS. There were many comments on this change, in part because the NRC specifically requested comments. Commenters expressed two clear opinions, one for and one against the change. The statements for the change refer to the high number of positive test results for opiates that are overturned as legitimate use by MROs. The statements against are that the cutoff levels and the 6-AM requirements suggested by HHS would eliminate virtually all positives for opiates except heavy, recent, heroin use. This would prevent the detection of individuals using opiates, such as codeine, in inappropriate ways (e.g., overdosing or being impaired from a codeine prescription while operating heavy machinery). Under the current program, even if the MRO determines that there is a legitimate medical reason for the test result, there is an opportunity to determine if there is a possible impairment issue that could affect safety.

Related Summary Comments: 9.3.1; 9.3.2

Effect on Industry:

Making the change would save some money for licensees who choose to use the higher cutoff levels because fewer opiate test results would need to be reviewed by the MRO. It could also result in failure of the program to identify in a timely fashion workers that may present a safety risk.

Recommendation:

Do not adopt change to opiate cutoff levels. Adopt HHS policy with respect to testing for 6-AM.

Rule Reference:

Proposed rule:

2.7(f) "On-site and Laboratory Screening Tests."

(1) For the analysis of urine specimens, any screening test performed by a licensee's testing facility and the screening test performed by an HHS-certified laboratory must use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. Pending HHS (SAMSHA) review and approval of non-instrumented immunoassay testing devices, such devices shall not be used to test for drugs of abuse in NRC regulated FFD programs. Non-instrumented devices may be used for the tests to determine specimen validity

required by §2.7(e). The screening test of breath for alcohol performed at the collection site must use a breath measurement device which meets the requirements of Section 2.7 (p) (3) of this appendix. The following cut-off levels must be used when screening specimens to determine whether they are negative for the indicated substances:

Screening test cut-off level (ng/ml)

Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites ¹	300
Phencyclidine	25
Amphetamines	1,000
Alcohol ²	0.04% BAC

¹25 ng/ml is immunoassay specific for free morphine.

²Percent, by weight, of alcohol in a person's blood shall be based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath.

In addition, licensees may specify more stringent cut-off levels. In such cases, the results of HHS screening tests must be reported for both levels. Only the more stringent tests need be conducted, and the results for the cut-off levels above may be calculated.

2.7(g) (2) All urine specimens identified as presumptively positive on the screening test performed by an HHS-certified laboratory must be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cut-off values listed in this paragraph for each drug, or at the cut-off values required by the licensee's unique program, where differences exist. All confirmations must be made by quantitative analysis. Concentrations which exceed the linear region of the standard curve must be documented in the laboratory record as "greater than highest standard curve value."

Confirmatory test cut-off level (ng/ml)

Marijuana metabolite ¹	15
Cocaine metabolite ²	150
Opiates:	
Morphine	300
Codeine	300
6-Acetylmorphine ³	10
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine ⁴	500
Alcohol ⁵	0.04% BAC

¹Delta-9-tetrahydrocannabinol-9-carboxylic acid.

²Benzoyllecgonine.

³Test for 6-AM when the confirmatory test shows a morphine concentration exceeding 2,000 ng/ml.

⁴Specimen must also contain amphetamine at a concentration ≥ 200 ng/ml.

⁵Percent, by weight, of alcohol in a person's blood shall be based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath.

In addition, licensees may specify more stringent cut-off levels. In these cases, the results must be reported for both levels. Only the more stringent tests need be conducted, and the results for the cut-off levels above may be calculated.

A.18 Section 2.8 — Quality Assurance and Quality Control: Exempt Small Businesses

Potential Modification:

Exempt small businesses that supply contractor employees to licensees from certain provisions regarding blind performance testing if they conduct preaccess testing of their own employees.

Background:

Commenters requested exemption for vendors and contractors so that they can conduct preaccess testing for their personnel prior to their reporting to the site. The rule requires that any licensee, contractor, or vendor that conducts testing under Part 26 to submit blind performance test specimens to their HHS-certified laboratory. If a contractor desires to take future credit for any test, then that test must meet Part 26 standards. This revision would exempt small contractors and vendors from sending blind performance test specimens through the HHS-certified laboratory they use for preaccess tests. The NRC staff believes, however, that only relatively large contractors or vendors actually conduct their own testing and that there are very few of these. Therefore, this change is not needed to accommodate small companies.

Related Summary Comments: 7.1.6

Effect on Industry: None

Recommendation:

Do not adopt change. Contractors and vendors can be tested under another program meeting the standards of Part 26 and which has been reviewed and accepted by a licensee. Also, sample collection and testing of the contractor/vendor specimen by any HHS-certified laboratory that is under contract to any licensee would be acceptable.

Rule Reference:

Proposed Rule:

(2) During the initial 90-day period of any contract with an HHS-certified laboratory (not including rewritten or renewed contracts), each licensee shall submit blind performance test specimens to the laboratory within the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 100 specimens) or 30 blind performance test specimens, whichever is greater. Following the initial 90-day period, a minimum of 3 percent of all specimens (to a maximum of 25) or 10 blind performance test specimens, whichever is greater, must be submitted per quarter. Licensees should make an attempt to submit blind performance test specimens during the initial 90-day period and per quarter thereafter at a frequency that corresponds with the submission frequency for other specimens.

A.19 Section 2.8 — Quality Assurance and Quality Control: FDA Good Practices

Potential Modification:

Add language to Section 2.8(e) to require FDA registration or FDA “good manufacturing practices” for blind performance test specimens.

Background:

Commenters point out that a significant number of problems have arisen regarding blind performance test specimens and that measures to prevent deterioration and clear quality controls for blind specimens are not required by HHS.

Related summary comments: 9.4.8

Effect on Industry:

It would probably raise the cost of doing blind performance testing but also might reduce the costs of addressing problems with the blind performance test specimens.

Recommendation:

Do not adopt change but recommend as a good practice that may save licensees money in the long term. NRC will revisit if SAMSHA or FDA address this in their requirements.

Rule Reference:

Proposed rule:

(e) "Licensee Blind Performance Test Procedures."

(1) Licensees shall only purchase blind quality control materials that:

(i) Have been certified by immunoassay and GC/MS; and

(ii) Have stability data which verify performance of those materials over time.

(2) During the initial 90-day period of any contract with an HHS-certified laboratory (not including rewritten or renewed contracts), each licensee shall submit blind performance test specimens to the laboratory within the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 100 specimens) or 30 blind performance test specimens, whichever is greater. Following the initial 90-day period, a minimum of 3 percent of all specimens (to a maximum of 25) or 10 blind performance test specimens, whichever is greater, must be submitted per quarter. Licensees should make an attempt to submit blind performance test specimens during the initial 90-day period and per quarter thereafter at a frequency that corresponds with the submission frequency for other specimens.

(3) Approximately 50 percent of the blind performance test specimens must be blank (i.e., certified to contain no drug) and the remaining specimens must be positive for one or more drugs

per specimen in a distribution so that all the drugs for which the licensee is testing are included in approximately equal frequencies of challenge. The positive specimens must be spiked only with those drugs for which the licensee is testing. In addition, 10 percent of the positive blind specimens must be appropriately adulterated or diluted and spiked to between 60 and 80 percent of the screening cut-off values established by Section 2.7(f) of this appendix, or of any lower cut-off values established by the licensee, to challenge the laboratory's ability to determine specimen validity and perform special processing, as required by Section 2.7 (e) of this appendix.

ATTACHMENT D
RESPONSES TO PUBLIC COMMENTS

**Fitness For Duty in the Nuclear Industry:
Responses to 1996 Public Comments**

Abstract

The Nuclear Regulatory Commission published for public comment on May 9, 1996 proposed amendments to its current Fitness-for-Duty Program requirements in 10 CFR Part 26 (61 FR 21105). The proposed amendments were intended to increase compatibility with the HHS Mandatory Guidelines; substantially reduce licensees' cost of implementing the rule; enhance overall program integrity, effectiveness, and efficiency; and help to ensure the continued protection of public health and safety. This report summarizes public comments received on the proposed rule amendments and provides the staff resolutions of the issues raised by the commenters.

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Acknowledgements

The NRC would like to acknowledge the valuable contributions that several people and organizations have made to the preparation of this document. The comments on the proposed rule revisions submitted by the Nuclear Energy Institute, individual licensee representatives, and other members of the public were very thoughtful and constructive. The comments submitted by Dr. Joseph H. Autry on behalf of the Department of Health and Human Services and by Theodore F. Shults of the American Association of Medical Review Officers were particularly useful. The NRC also thanks Dr. Arthur Zebelman of Dynacare Laboratories for his helpful technical observations throughout this rulemaking process. As the responses in this document make clear, the NRC has further improved the rule by adopting several of these commenters' recommended rule revisions. The NRC would also like to acknowledge the valuable assistance provided by Pacific Northwest National Laboratory (PNNL) and Battelle staff in the analysis of the comments and the preparation of this document's manuscript. In particular, the NRC recognizes the valuable contribution of Dr. Nancy E. Durbin and Thomas F. Grant, who served as PNNL and Battelle project managers, as well as Michelle Silbernagel, Antoinette Slavich, Alice Forsythe, Dr. Jennifer Macaulay, Kate Lynch, Anita Freeze, and Susan Czarny.

1.0 Introduction

This document presents the public comments received in response to the U.S. Nuclear Regulatory Commission's (NRC) proposed revisions to Part 26 of 10 CFR, entitled "Fitness-for-Duty Program" and the staff resolution of those comments.

1.1 Background

The NRC published its final rule, 10 CFR Part 26: Fitness-for-Duty Programs, in the Federal Register (54 FR 24468) on June 7, 1989. The rule required each licensee authorized to operate or construct a nuclear power reactor to implement a Fitness-for-Duty (FFD) Program for all personnel having unescorted access to the protected area of its plant. This rule became effective on July 7, 1989, with an implementation date of January 3, 1990. As published on June 3, 1993 (58 FR 31467), and effective on November 30, 1993, Strategic Special Nuclear Materials Licensees were added to the scope of the rule.

The NRC published for public comment proposed modifications to the current FFD requirements on May 9, 1996 (61 FR 21105). The proposed amendments were intended to ensure compatibility with changes made to the Department of Health and Human Services (HHS) testing guidelines, to reduce unnecessary burdens on licensees and their employees while fulfilling the purpose of the rule, to add a limited number of new requirements to ensure the continued effectiveness of the rule (e.g., measures to reduce the potential for subversion of the testing process and to assure that the appeals process is available to all individuals covered by the rule), to clarify the Commission's original intent in several areas, and to deal with administrative matters.

1.2 The Comments

The comment period expired on August 9, 1996, however, the NRC accepted additional comments through September 1996 as being practical without interrupting the review process. Thirty-six comment letters were received. A public meeting, announced in the Federal Register (61 FR 24731, May 16, 1996), was held in Rockville, MD on June 12, 1996. This meeting was transcribed and the comments made during this meeting have been considered in this document. In addition, a meeting at the Region I Fitness for Duty Association to discuss proposed changes to the FFD rule was held on May 16, 1996. Although this meeting was not transcribed, a summary of the issues raised at this meeting was produced and these comments are also addressed in this document. Comments from two other letters were considered. One was additional information clarifying an earlier letter. The other was a letter sent in response to a previous Federal Register notice related to this rulemaking.

All comments were reviewed, categorized, and addressed. The reviews resulted in a total of over 1,000 unique comment-category combinations entered in the database. The number of unique comment-category combinations in individual letters ranges from 1 to 176. As will be discussed in more detail in Chapter 2, individual comments that made the same or similar points were grouped together and all individual comments were paraphrased for presentation in this document.

1.3 Organization of the Report

This comment resolution document is organized into 19 chapters. After this chapter, Chapter 2, Methodology, and Chapter 3, Public Responses to Specific NRC Questions, subsequent chapters on substantive topics are presented as listed in the Table of Contents. Each of these substantive chapters presents summarized comments with accompanying responses. Appendix A provides a list of the identification numbers for each commenter or comment document and the individual or organization submitting the comment or document. Appendix B provides an alphabetized list of commenters with their identification number and the sections of the document that summarize and respond to their comments. Commenters can use these appendices to identify the sections where their comments are addressed.

In many cases the responses refer the reader to other documents for further or more detailed information regarding a response. These documents include:

NUREG 1354	Fitness for Duty in the Nuclear Power Industry: Responses to Public Comments
NUREG 1385	Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions
NUREG/CR 5227	Fitness for Duty in the Nuclear Power Industry: A Review of Technical Issues
NUREG/CR 5227,	Fitness for Duty in the Nuclear Power Industry: A Review of Supp. 1
Technical Issues	
NUREG/CR 5758, Vols 1-6	Fitness for Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports
NUREG/CR 5784	Fitness for Duty in the Nuclear Power Industry: A Review of the First Year of Program Performance and an Update on the Technical Issues
NUREG/CR 6470	Fitness for Duty in the Nuclear Power Industry: Update of the Technical Issues, 1996.

2.0 Methodology

This section outlines the methodology used in responding to the public comments. The methodology includes provisions for logging of letters received and of comments made during public meetings, the identification of specific comments within each letter, the combination of similar comments from different letters into summary comments, and the writing of responses to each summary comment. This section describes the quality assurance procedures that were used at each step to assure that comments received fair consideration.

2.1 Logging of Letters and Comments

The NRC received and docketed a total of 36 letters containing comments in response to the notification of the proposed rule modifications, one letter in response to a previous FRN related to this rulemaking, and an additional letter provided clarification to a letter previously received. Also, a list of questions posed at the Region I FFD Association Meeting was produced and used as comments. The transcript of the public meeting on June 12, 1996, was used to identify comments and produce a unique number for each commenter at the meeting.

Docketed letters, two additional letters, and meeting transcripts were sent to Battelle's Seattle Research Center for analysis. The sequential docket numbers have been retained as the identification numbers used in this report. The documentation items from the two meetings and two letters were not assigned docket numbers under this rulemaking by the NRC. Upon receipt of these items, Battelle assigned them sequential identification numbers. These identification numbers begin at 5001 for the letter received in response to a related Federal Register notice, the Region I FFD Association Meeting (no persons identified), and the supplemental information to comment letter #8; and begin at 6004 for each person providing a comment at the public meeting on June 12, 1996.

2.2 Comment Identification

The key to an accurate and fair treatment of the commenter's concerns is the identification of what constitutes a comment. Three contractor staff members with detailed knowledge of the current fitness-for-duty rule and proposed modifications were assigned the task of comment identification. Using a categorization scheme based on the summary comment sections of NUREG-1354, the reviewers examined an identical subset of the letters to identify the separate and distinct points that the writers had made. The results were compared across the three reviewers to refine the initial categorization scheme and to assure that the reviewers would identify the same comments and assign them to the same categories.

Once the categorization scheme was finalized and reviewed by the NRC staff, the letters and transcripts were divided among the three reviewers. The reviewers annotated copies of the letters and transcripts to identify the distinct comments and, for each comment, the category (or, in some cases, categories) that applied to the comment. The letters and transcripts were scanned into electronic formats and the distinct comments and their assigned categories were entered into a computerized database system. Within this database, each comment-category combination was identified by a unique number. The reviews resulted in a total of over 1,000 unique comment-category combinations entered in the database. The number of unique comment-category combinations in individual letters ranges from 1 to 176.

2.3 Comment Summarization

Some of the comments received were identical or very similar to one or more of the other comments or represented different aspects of the same issue. To make this document a manageable length, and to improve its readability and usefulness to the public, similar comments were grouped into summary comments. Care was taken in the grouping process to preserve the entire range of commenters' points or questions.

As a first step, comments under each category were reviewed to determine which of the individual comments could be paraphrased into summary comments. Then a team of three contractor staff members reviewed the summary comments and their respective individual comments to assure that each summary comment captured the points or questions of the individual comments and that each individual comment was assigned to the appropriate summary comment. Features of the database were used to additionally assure that each individual comment was assigned to a summary comment and all summary comments had individual comments assigned to them. All the summarized comments were reviewed by two senior contractor staff members.

Several comments addressed issues that could be characterized by more than one summary comment category. These comments were represented in each of the relevant summary comments and references were made to discussions in related summary comments.

As a final quality assurance check, one contractor staff member verified that each comment identified in a random sample of letters and transcripts was addressed in a summary comment.

2.4 Comment Responses

Once the task of creating summarized comments was completed, the next task was to provide a response to each of the summarized comments. Staff were assigned to comment summaries based on their knowledge of the subject matter and their familiarity with the rule. Working with the NRC staff, contractor staff developed draft responses that were then passed on to a senior NRC staff member for review. Necessary changes were made to the draft responses and the comment-response packages were sent to the NRC for review by the NRC staff directly responsible for the rule development. Changes were made where needed to clarify the NRC's intent. The final comment-response document was provided to the NRC for publication with the final rule.

3.0 Public Responses to Specific NRC Questions

In 61 FR 21107 and 21108 the NRC solicited public comment on eight specific issues regarding new or changed requirements that the NRC was considering. Several commenters responded to this request. In addition to these eight questions, additional questions were presented in the general discussion section of the Federal Register notice. The specific questions and summaries of public answers to those questions are provided below. Commenters' concerns regarding each of the questions are also addressed in specific comments throughout this document. References to sections that provide summary comments and responses related to each of the questions are provided.

The NRC requested public comment on the following issues.

3.1 NRC Question One: Backfitting

This section presents the NRC's backfit-related questions, summaries of commenters' answers, and the NRC's responses to those answers.

(a) Would any of the proposed changes, groups of related requirements (e.g., modifications to prevent subversion of the testing process, further ensure the accuracy and integrity of testing, clarify actions for removal), or the rulemaking as a whole provide a substantial increase in the overall protection of the public health and safety or the common defense and security?

Summary of comments:

Most commenters who responded to this question stated that the proposed changes, considered individually or as a whole, would not provide a substantial increase in the overall protection of the public health and safety. Three commenters either stated that the changes would as a whole provide an incremental improvement in the protection of the public health and safety or enhance achieving the objectives of the FFD program. (Identification numbers: 1, 3, 7, 10, 12, 14, 18, 20, 30, 32, 6006)

NRC response:

The NRC has re-evaluated the proposed changes in light of the public comments. As set forth in "Backfit Analysis" in the Statement of Considerations for the final rule, the Commission has determined that the FFD rule should be evaluated for backfitting as an integrated whole, and has concluded that the rule in the aggregate constitutes a cost-justified substantial increase in protection to public health and safety. A discussion of individual changes with respect to backfit is contained in "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness for Duty Rule (10 CFR Part 26)," which is available for inspection and copying for a fee at the NRC Public Document Room.

Related summary comments and NRC responses may be found at: 19.2.2, 19.2.3, 19.2.8

(b) Are the groupings and subgroupings of the changes contained in the Backfit Analysis section of this Federal Register notice appropriate and are the changes categorized properly?

Summary of comments:

While not referring explicitly to the Commission's categorization of the proposed rule changes in its Federal Register notice of May 9, 1996, several commenters expressed the opinion that most of the proposed changes would create reasonable and appropriate clarifications of rule requirements or reductions of licensee burden and should be adopted as soon as possible, other commenters said that proposed revisions would increase licensee burden. Commenters expressed the opinion that the backfit rule applies only to new obligations imposed by the NRC, and one commenter specifically said that it is the mandatory nature of the regulatory change that controls applicability of the rule. Where a regulatory requirement or the implementation of a revision is not mandatory but is left to licensees' discretion to continue implementing the current requirement or to adopt the change, such changes are not backfits. (Identification numbers: 3, 7, 10, 13, 20, 27)

NRC response:

The NRC has thoroughly reviewed all of its proposed revisions with respect to the application of the backfit rule and has concluded that each revision fits into at least one of the following classifications, as discussed in the "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule 10 CFR Part 26):"

- 1) Clarifications. Several revisions will clarify current requirements to assure consistent understanding and implementation of the Commission's original intent for these requirements. Without changing the requirements stated in these sections, these revisions would remove the ambiguities that produced the licensee's uncertainty. The backfit rule does not apply to revisions that leave current requirements unchanged.
- 2) Administrative matters. A few revisions make minor administrative changes, such as correction of typographic errors, correction of inconsistencies, relocating requirements from one section to another, and combining existing requirements into a single section. Administrative matters are not subject to Backfit Rule requirements.
- 3) Permissive relaxations. Several revisions permit, but not require, relaxations of current requirements (i.e., licensees are free to either comply with current requirements or adopt the relaxed requirements as an alternative). The backfit rule does not apply to rule revisions that provide permissive relaxations of current requirements.
- 4) Information collection and reporting requirements. A few revisions modify information collection and reporting requirements, which are not considered to be backfits, as set forth in the Committee to Review Generic Requirements (CRGR) charter.
- 5) Compliance exceptions. Several revisions are necessary to bring licensees into compliance with existing Commission requirements or the Commission's clearly stated intent in promulgating the requirement. In addition, some of the revisions modify current requirements where there is evidence that the current version of the standard is not achieving the purpose that the Commission had when it originally promulgated the rule. These revisions are exceptions to the backfit rule, as specified in 10 CFR 50.109(a)(4)(i).
- 6) Worthwhile changes to be adopted as Backfit Rule Exceptions. Some of the revisions are recommended for consideration for adoption as an exception to the backfit rule because they are worthwhile changes. The Commission indicated in the SRM dated June 30, 1993, that it would consider worthwhile changes on a case-by-case basis as an exception to the

"substantial increase" in safety standard, as long as they have been subject to public notice and comment, as these revisions have.

However, as set forth in the "Backfit Analysis" in the Statement of Considerations for the final rule, the Commission has determined that the FFD rule should be evaluated for backfitting as an integrated whole, and has concluded that the rule in the aggregate constitutes a cost-justified substantial increase in protection to public health and safety.

Related summary comments and NRC responses may be found at: 19.2.4

(c) Are the changes in Group III worthwhile and necessary to better accomplish the FFD rule's objective, clarify the rule's existing requirements, and reduce ambiguities?

Summary of comments:

Although commenters did not specifically refer to the Commission's categorization scheme, some commenters supported the Commission going forward with those rule revisions that serve to better accomplish the rule's objectives and clarify current requirements. One commenter stated that the proposed revisions would significantly improve the effectiveness of the FFD program and that the backfit rule should not apply to this rulemaking. The remainder of these commenters said, however, that the backfit rule requires the NRC to conduct an analysis of the effects of those revisions that would create new licensee burden. (Identification numbers: 7, 20, 29)

NRC response:

The NRC has prepared a detailed analysis of the backfitting applications of each of the proposed changes, which may be found in "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26)," which is available for inspection and copying for a fee at the NRC Public Document Room.

Related summary comments and NRC responses may be found at: 19.1.2, 19.1.3, 19.2.3, 19.2.4

(d) Does the rule as a whole not constitute a backfit since the rule's cumulative effect is to ease licensee burdens or leave them essentially the same, rather than to increase them?

Summary of comments:

One commenter recommended that the backfit rule should not be applied to the proposed amendments because the rulemaking as a whole would provide an incremental improvement and reduce licensee burden. Another commenter contended that the proposed revisions would significantly improve the effectiveness of the FFD program and that the backfit rule should not apply to this rulemaking. This commenter justified that contention by observing that drug abuse is a chronic and dynamic problem, and that rather than remaining static, FFD programs must instead keep pace with changes in drug abuse patterns, methods of drug detection avoidance, and new technologies; therefore technical changes to FFD programs are essential to maintain effectiveness. The commenter asserted that the backfit analysis requirement is an obstacle to maintaining effectiveness, the backfit rule essentially requires that the program come close to being ineffectual before regulatory changes can be made, and that safety programs should not have to run to the brink of failure before corrective action can be taken.

Other commenters urged the Commission to proceed with adopting those revisions that would not increase burden, but justify those revisions that would increase burden with a backfit analysis. Some commenters expressed the opinion that most of the proposed changes would create reasonable and appropriate clarifications of rule requirements or reductions of licensee burden and should be adopted as soon as possible. These commenters stated that adoption of such changes does not require an exception to the backfit rule because no new burden would be imposed on licensees. Several commenters expressed the opinion that the backfit rule applies only to new obligations imposed by the NRC. One of these commenters specifically said that it is the mandatory nature of the regulatory change that controls applicability of the rule. If a reduction in a regulatory requirement or the elimination of a regulation is not made mandatory but is instead left to licensees' discretion whether to continue implementing the current requirement or adopt the change, the change is not a backfit. (Identification numbers: 3, 7, 10, 13, 30)

NRC response:

The NRC agrees with the commenters that the backfit analysis requirement does not apply to specific revisions that either relax current requirements, are neutral with respect to current requirements, or that clarify, but do not change, existing FFD program requirements.

Related summary comments and NRC responses may be found at: 19.1.2, 19.1.3, 19.2.2, 19.2.4, 19.2.5, 19.2.6, 19.2.7

(e) Does anyone subject to the rule not object to the new requirements in view of their perception of an overall benefit and, if so, would their non-objection be grounds for not applying the backfit rule?

Summary of comments:

The one commenter who addressed this specific question stated that the NRC's authority to waive the backfit rule is limited and that a backfit analysis should be performed for any new requirement meeting the definition of a backfit. Although not specifically addressing this question, other commenters stated in general terms that the NRC must apply backfit analysis to those proposed revisions that would increase licensee burden even if the overall effect of the revisions would be to decrease burden. (Identification numbers: 7, 10, 13, 20, 30)

NRC response:

Since there were commenters subject to the rule who objected to some of the new requirements, the NRC will not rely upon a "non-objection" as a basis for not applying the backfit rule.

Related summary comments and NRC responses may be found at: 19.2.4, 19.2.7

(f) Although the NRC believes that the proposed specific changes to the FFD rule would be the most efficient method of accomplishing the regulatory objectives of the changes, are there any viable alternative approaches that should be considered, particularly with respect to the proposed changes in Group III B?

Summary of comments:

One commenter stated that the proposed amendments are the most efficient method of accomplishing the regulatory objectives and alternatives, such as regulatory or industry developed guidance, would not solve existing regulatory problems. Another commenter supported the development of industry-sponsored guidance based upon discussions between the NRC staff and industry representatives. This commenter also stated that, if Part 26 were to become more performance based, then industry guidelines would be appropriate and probably necessary. Another commenter urged the NRC to examine other vehicles such as a regulation guide or generic letter. One commenter stated that many of the proposed amendments are unnecessary and did not believe that the need for additional requirements had been sufficiently established while another commenter did not agree that the proposed revisions would reduce the cost of implementation, enhance program integrity, effectiveness and efficiency and help ensure the continued protection of public health and safety in the most efficient and effective way. However these two commenters did not suggest alternatives. (Identification numbers: 3, 7, 12, 17, 6006)

NRC response:

After consideration of alternative approaches suggested by commenters, the NRC has concluded that rulemaking is the only effective vehicle for making these changes. Rule change is favored because it may reduce interpretive debates. Collective bargaining and judicial reviews also require clear public policy that is provided by rulemaking. The NRC's earlier experience with industry developed guidelines used to implement an NRC policy statement was unsatisfactory, mostly because of these impediments, and was the primary reason the Commission developed Part 26.

Related summary comments and NRC responses may be found at: 5.3.1, 5.3.2, 19.1.1, 19.1.4, 19.2.4

(g) Could the rule be less specific in stating the requirements?

Summary of comments:

One commenter expressed an opinion that the level of specificity in stating the requirements is appropriate and needed as discussed in the May 9, 1996 Federal Register notice beginning at 61 FR 21106. (Identification number: 3)

NRC response:

The NRC agrees with the commenter. The past seven and one-half years of program implementation have indicated the need for the FFD rule to be quite specific in establishing several FFD program requirements. The many questions as to the meaning of certain rule sections plus continuing licensee FFD program administrator requests of the NRC staff for other guidance attest to the need for this level of specificity. The NRC is also aware, however, that licensee programs can be most effective in fulfilling some FFD program requirements if they have the flexibility to find the most effective and efficient means of meeting those requirements. In some cases, the NRC has relaxed the rule's specificity to allow needed flexibility. The NRC has taken both of these considerations into account as it has proposed and adopted the revisions to the FFD rule.

Related summary comments and NRC responses may be found at: 4.3.1, 7.6.3, 19.1.1

3.2 NRC Question Two: Consistency with HHS Guidelines

Should the NRC revise Appendix A to 10 CFR Part 26 to incorporate revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs recently adopted by the Department of Health and Human Services (June 9, 1994; 59 FR 29908)? The Commission proposes adoption of the changes to the HHS Guidelines. In most instances, the HHS Guidelines have been adopted as published by HHS; however, in some cases modifications are proposed to allow compatibility within the framework of the original FFD rule (e.g., on-site testing provisions dictated differences in minimum specimen volume, minimum number of blind performance specimens, on-site determination of the validity of specimen). The NRC desires to be consistent with the HHS Guidelines, absent a compelling reason why a departure is necessary.

Summary of comments:

Several commenters agreed that the revisions to the HHS Guidelines should be incorporated to be consistent. However many qualified their responses. One commenter recommended that the NRC adopt modifications to some of the HHS Guideline revisions to allow compatibility with the original FFD rule. Another commenter stated that licensees should be allowed to adopt additional or more stringent requirements as appropriate for their own circumstances. A third commenter stated there should be not be any differences and that there should be included a statement that all future revisions to the HHS Guidelines would be automatically incorporated into Appendix A so that nuclear industry testing would be consistent with the recommended Federal testing process used by other regulatory agencies. Another commenter stated that changes to ensure compatibility with the HHS Guidelines would provide consistency with other federal programs. One commenter stated that there are major differences between the policies proposed by the NRC and the HHS Guidelines, so in order to be less confusing the NRC should only refer to parts of the HHS Guidelines it wants to accept rather than stating it wants to be consistent and then allow changes to the HHS Guidelines (e.g., the NRC directs licensees to use the HHS testing levels and then allows licensees to use different levels). (Identification numbers: 3; 7; 10; 12; 14; 20; 25; 30; 32)

NRC response:

The NRC concurs with the commenters' views as to the value of providing consistency with the HHS Guidelines revisions to the extent practicable, while acknowledging the need to make adjustments to some of the Mandatory Guidelines revisions to respond to the requirements specific to the nuclear industry's needs. The NRC believes that consistency across Federal programs is desirable when practicable. However, the NRC concludes that some program differences between Part 26 requirements and those of other federally mandated programs are necessary. While much of the HHS Guidelines has been adopted as published by HHS, the NRC has made some modifications to achieve compatibility with the NRC's responsibilities for assuring public health and safety. Adoption of a procedure that would automatically incorporate HHS Guideline changes would not allow the consideration of particular safety and program issues specific to the nuclear industry.

Related summary comments and NRC responses may be found at: 4.1.1, 4.1.2, 4.1.5, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 9.4.3, 9.5.2, 9.5.10, 11.3.2

3.3 NRC Question Three: Alcohol Testing Alternatives

With respect to the discussion of the proposed changes to section 26.24, are there any alternative techniques for testing for alcohol that should be considered for adoption by the NRC?

Summary of comments:

Several commenters stated that at this time they are aware of no alternative alcohol testing techniques that appear to be superior to the National Highway Traffic Safety Administration (NHTSA)-approved evidential-grade breath analysis equipment that the FFD rule has always required. A few commenters recommended that the NRC relax its current requirements by approving the use of non-evidential breath testing devices for alcohol screening testing. Another commenter noted that court decisions have approved the use of NHTSA-approved evidential breath testing and that, even if the use of other equipment for screening testing was allowed, evidential-grade breath analysis equipment would still be needed to achieve legally recognized confirmatory testing.

Commenters also made other specific recommendations regarding alcohol testing procedures. One commenter thought blood testing for alcohol to be unnecessary and recommended that it be eliminated from the rule or allowed only in extreme cases (e.g., post-accident testing when individual is unconscious). Another commenter requested that the NRC consider devices which use two independent testing technologies (electro-chemical fuel cell and 9.5 micron infrared spectroscopy) for use in confirmatory testing or for both screening and confirmatory testing.

NRC response:

The NRC believes that the current requirements for use of evidential devices that conform to NHTSA's Model Specifications for Evidential Breath Testing Devices (58 FR 48705; September 17, 1993 and 49 FR 48854; December 14, 1984) are appropriate for both screening and confirmatory tests, and will continue to require the use of such devices. All NRC regulated programs currently have such devices in use. The approval of non-evidential testing devices by DOT, for example, provides more flexibility for initial testing due to the nature of the industry it regulates, which requires more mobile testing mechanisms. Such mobility is generally not an issue in NRC regulated programs. The NRC is satisfied with the current requirements and the devices on NHTSA's Conforming Products List (CPL) for evidential devices that conform to the model specifications (the last CPL update was published in 61 FR 3078; January 30, 1996), and believes that the use of non-evidential grade equipment may lead to false negative test results. Therefore, the alcohol screening procedures will not be changed to permit non-evidential grade equipment.

The NRC recognizes the difficulties associated with blood collection but continues to believe that the provision for blood testing provides desirable reassurance to individuals regarding their appeal rights and increased legal defensibility of all positive alcohol results, including those appealed without the drawing of blood.

Related summary comments and NRC responses may be found at: 10.1.1, 10.1.2, 10.3.1

3.4 NRC Question Four: Additional Information

During past years of program operations, several parties have recommended that the NRC consider obtaining certain types of information in addition to that currently required to be submitted under the provision of section 26.71(d). They believe that the Commission could use such information to better manage its FFD program oversight responsibilities, which includes formulation of public policy. The specific additional types of information and their potential use by the NRC are described in the discussion of proposed revisions to section 26.71 but are not incorporated into the proposed changes to the text of the rule. The NRC requests public comment on whether the licensees should be required to collect, analyze, and submit to the NRC such additional types of information.

The NRC also noted in another section of the discussion that having access to this information would enable the NRC to gain a clearer and more detailed understanding of the actual operation of the programs. This information would also be useful for purposes of revising the regulation or providing guidance so that the general performance objectives stated in section 26.10 can be better achieved. The NRC, therefore, also seeks public comment as to whether section 26.71 (d) should be revised further to require that these types of information be collected and analyzed by licensees and submitted to the NRC. The NRC also seeks public comment as to whether the NRC should develop a management information system similar to that promulgated by DOT and its operating administrations (58 FR 68194 through 68285; December 23, 1993).

Summary of comments:

One commenter stated that there is no demonstrated value added and no potential improvements derived if the NRC collects additional information and that requiring unnecessary data may be contrary to EAP confidentiality and the Paperwork Reduction Act. Another commenter stated that the proposed data collection is in conflict with confidentiality of EAPs and is not a deterrent to drug and alcohol use. Two commenters stated that there should not be requirements for additional data unless there are specific benefits identified such as an increase in protection of public health and safety or the information can be used by the utilities. Two commenters stated that the added administrative burden would be costly and not effective. Two commenters stated that the additional information would not increase overall protection of the public health and safety. Another commenter stated that the information can be made available during inspections and that the value added does not warrant the additional burden to the licensees. (Identification numbers: 7; 10; 14; 15; 20; 29; 32)

NRC response:

The NRC has decided not to add requirements for additional information to be routinely collected to the regulation at this time beyond the types of additional information it originally proposed. The NRC may in the future decide to collect information of the type discussed for purposes of developing program performance indicators. The proposed clarification of significant FFD events that must be reported and the addition of the number of subversion attempts to current program performance reporting requirements will be retained in the final rule.

Related summary comments and NRC responses may be found at: 17.1.1, 17.2.6, 17.2.13

3.5 NRC Question Five: Specimen Validity

The NRC is proposing to add a new section 2.7(e) to Appendix A that would require testing to determine specimen validity (i.e., detect evidence of adulteration or dilution) before performing a screening test on site (if appropriate) and at the HHS laboratory. This would be an adaptation of a change HHS made to its guidelines in June, 1994. However, not all dilute specimens are the result of attempts to avoid detection. Hence, to minimize the probability of incorrect conclusions from such events, suspect specimens, including those with abnormal specific gravity (SG) would be subject to screening and confirmation testing using the limit of detection that the laboratory is capable of performing. The Commission requests comments regarding this change, and, in addition, requests comments on three other revisions to detect evidence of adulteration or dilution that are under consideration:

Summary of comments:

The comments responding to the proposed revisions regarding testing for specific gravity and at laboratory limits of detection (LOD) included a wide range of issues. Several commenters opposed these changes citing increased costs, problems with the technical defensibility of the procedure, problems of cross-contamination during testing, differences in LOD standards among laboratories that may cause inconsistent test results, and contended that HHS does not sanction the procedure. Other commenters supported the new requirements and offered suggestions regarding improvements in implementation and/or suggestions for additional tests for specimen validity, such as pH and creatinine testing. Supporters noted that the rule has always required specimen validity testing and that clearer guidelines would increase consistency and decrease successful subversion. Several commenters requested information regarding whether the addition of specific gravity testing would affect the application of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to licensee testing programs. Both positive and negative comments were also received regarding testing at LOD. Commenters opposing the policy cited concerns about increased costs, the technical defensibility of the procedure, problems with cross-contamination during testing, desire for HHS guidance, and the potential that inter-laboratory differences in standards may create legal difficulties. Supporters of LOD testing noted that it was currently being used under the HHS, NRC, and DOT testing guidelines for retesting of specimens.

NRC response:

The NRC appreciates the time and care that commenters took to respond to this question. Commenters provided significant input. Although specimen validity testing has always been included in Part 26 (see sections 2.1(e), 2.4(g), and 2.7(d) of Appendix A), the NRC has determined that there are substantial benefits of providing minimum requirements for this testing and has decided to adopt changes made to the HHS Mandatory Guidelines and changes to laboratory procedures recommended by HHS under its National Laboratory Certification Program (NLCP). NLCP Program Document #35 provides recommended guidance for the HHS certified laboratories to use in conducting tests to detect evidence of adulteration and dilution; if such testing is conducted, it should include creatinine, specific gravity, pH, and nitrites. To the extent they are used, these minimum requirements for determining specimen validity will increase consistency, decrease successful subversion, and will deter attempts to subvert the testing process through specimen adulteration and dilution.

Studies of the relationship between dilution and the presence of drug metabolites at or below cut-off levels indicate that, while dilute specimens are approximately ten times more likely to be positive, ninety percent of dilute specimens show no evidence of illegal drug use. In making this revision, the NRC is attempting to strike a balance that will maximize detection and deterrence of attempts to subvert the testing process through dilution while minimizing the impact on individuals who have dilute specimens for legitimate reasons. Testing of questionable specimens to identify lower concentration levels of drug or metabolite is intended to achieve both purposes. If a questionable specimen is found to contain illegal drugs or metabolites at the lower level of concentration, it is a violation of the licensee's FFD policy. No additional testing is necessary for this conclusion. (The MRO may determine in these situations both that the donor has attempted to subvert the testing process and used illegal drugs.) If the questionable specimen is negative at the lower level of concentration, the MRO has the option of determining that it is a true negative and reporting it as such, or of determining that there is still a question and more information (potentially including an observed recollection) is required.

In conjunction with these changes, the NRC believes it is appropriate to remove the requirement for recollection under direct observation in all cases where a specimen is found to be dilute. The process for determining specimen validity in a new section 2.7(e) of Appendix A will result in most specimens being determined to be either valid or invalid. When the MRO cannot determine if the specimen is valid or invalid, another specimen must be collected as soon as possible.

In response to commenters' discussion of difficulties and suggestions, the NRC has modified the LOD testing requirement as originally proposed. The modified requirements call for screening tests of specimens of questionable validity, e.g., that contain no detectable adulterants but show evidence of dilution by having creatinine, specific gravity, and pH values between a valid specimen and an invalid specimen. Those specimens that have responses that are greater than the negative control responses to the screening tests are to be tested with GC/MS at the laboratory's LOD. This change makes the process for testing specimens with questionable validity comparable to the process for the testing of valid specimens. Although the MRO will still review the results of tests of all specimens of questionable validity, under this change the MRO, with the additional evidence of no drugs found with LOD processing, may determine that there is no need for an observed specimen collection.

Related summary comments and NRC responses may be found at: 11.1.2 to 11.1.8, 11.2.1, 11.2.2, 11.2.3, 11.2.8, 11.2.9, 11.4.10

(a) Including pH and or creatinine as well as SG in the required testing to determine specimen validity;

Summary of comments:

Commenters noted that creatinine testing would be difficult onsite; other commenters suggested the use of specific levels for creatinine and pH. (Identification numbers: 7; 10; 14; 29; 32; 36; 5002; 6011; 6014)

NRC response:

Tests for creatinine, SG, pH, and nitrites are means of determining specimen validity. The NRC will, consistent with actions taken by HHS in NLCP Program Document #35, require testing for creatinine, SG, pH, and nitrites to determine specimen validity at the HHS-certified laboratories.

The NRC will require testing for creatinine, pH, and nitrites for specimens being tested on site. Onsite testing for these specimen characteristics may be accomplished by “dipsticks.”

Related summary comments and NRC responses may be found at: 11.2.2, 11.2.3, 11.2.8, 11.2.11

(b) Requiring tests to determine specimen validity (which might include SG, pH, and or creatinine) immediately after specimen collection at all sites and immediate collection of a second specimen from those individuals providing specimens with abnormal qualities.

Summary of comments:

One commenter responded directly to this question, suggesting that specimen validity should be conducted at the time of the collection whenever practical. Another commenter objected to immediate collection of a second specimen since there are many reasons other than attempted subversion for providing a dilute specimen. (Identification numbers: 10; 36)

NRC response:

The NRC has chosen not to require testing for specimen validity at licensees' collection facilities and immediate collection of a second specimen when a person submits a specimen with abnormal qualities. (The basis for immediate recollections are listed in § 2.4(g)(15)(ii).) Instead, specimen validity testing is to be conducted at licensees' testing facilities (for licensees performing onsite testing) and at HHS-certified laboratories for all specimens sent to the laboratories.

Related summary comments and NRC responses may be found at: 11.2.4, 11.2.7

(c) Requiring tests at one-half of the cut-off levels specified for each drug instead of at the HHS-certified laboratory's limit of detection for suspect specimens.

Summary of comments:

There were several comments related to whether the NRC should require testing at one-half the standard cut-off levels for suspect specimens. Two commenters disagreed with the proposal and one commenter recommended that the LOD be used for all testing and should be the standard. Another commenter recommended that the laboratory screening continue to be at the licensee-determined screening level with the HHS Mandatory Guideline level as a maximum cut-off level. (Identification numbers: 7; 14; 18; 25; 36; 5002)

NRC response:

The NRC concurs that the LOD levels achieved by each HHS-certified laboratory should be used for suspect specimens rather than one-half the cut-off levels specified by HHS for each drug. Because there is not an LOD for screening testing, the rule will now require that screening testing for suspect specimens include comparison to negative screening controls. Although LOD results are technically accurate and could be used for all testing, cutoff levels will continue to be used as a matter of policy to minimize the possibility of cross reactivity, passive inhalation, and similar challenges to the accuracy of test results. Furthermore, GC/MS testing, which would be needed for LOD testing, is quite expensive and is not needed when a less expensive screening test can accurately determine that a specimen is clearly negative.

Related summary comments and NRC responses may be found at: 4.2.6, 9.3.4; 9.3.5; 11.2.10

3.6 NRC Question Six: Testing Issues

With respect to the discussion of the proposed changes to section 2.7 of Appendix A:

(a) Should the NRC require tests for agents that can be added to urine as an attempt to mask THC (marijuana) or other drugs?

Summary of comments:

The NRC received a number of comments regarding whether testing for agents that can be added to urine specimens to mask the presence of drugs or drug metabolites. Some commenters objected to any regulatory requirements for such testing, preferring that any testing be covered by industry guidelines. Additional commenters noted that, if such testing was deemed necessary, it should be mandated by HHS for HHS regulated laboratories rather than by the NRC. Other commenters supported requirements for testing for masking agents. (Identification numbers: 6; 7; 9; 10; 14; 20; 23; 25; 32; 5002; 6011)

NRC response:

With the exception required testing for nitrites (see discussion under item 3.5, above), the NRC will not require, but will continue to allow, testing for masking agents. Licensees are expected to pursue reasonable means of determining whether specimens are valid for testing. Tests for specific masking agents provide detailed information regarding the basis for an invalid specimen which are not necessarily required to meet the need for specimen validity testing. It is sufficient to determine that the specimen is not valid, and to impose sanctions, in accordance with written policy, for such determinations.

Related summary comments and NRC responses may be found at: 4.2.6, 4.2.9, 11.2.5, 11.4.1, 11.4.9

(b) Should the NRC raise the cut-off levels for screening and confirmation tests for opiates to reduce the laboratory-confirmed positives for opiates that the medical review officer (MRO) determines to be negative? Given the high level of concern for safety in the nuclear industry, should the NRC retain the current levels, even if HHS should raise the levels for "demand reduction" programs covered by its Guidelines as it proposed on November 16, 1995 (60 FR 57587)?

Summary of comments:

There were many comments in response to this question. Commenters expressed two clear and differing opinions. The opinion differences were not based on differences in interpretation of the empirical evidence, but were regarding the appropriate basis for making a decision. One opinion focused on the high cost of the current cut-off levels. The opinion expressed by these commenters was that the NRC should adopt the proposed higher cut-off levels for opiates and the additional criteria regarding the need for 6-AM testing because of the high number of laboratory confirmed positive test results at the current cut-off levels that are determined to be legitimate use by the MRO. Commenters supporting this view noted the high level of expense and low level of value in the work necessitated by these outcomes. The second opinion expressed focused on the potential for false negative test results with the higher cut-off levels for opiates. These

commenters argued that the higher cut-off levels and 6-AM requirements proposed by HHS would virtually eliminate all positives for opiates except heavy, recent, heroin use. This would prevent the detection of individuals using opiates, such as codeine, in inappropriate ways (e.g., taking more than prescribed or operating heavy equipment when taking a legally prescribed, but impairing, drug). (Identification numbers: 6; 7; 9; 10; 20; 23; 32; 36; 5002; 6014)

NRC response:

The NRC has carefully considered the cost of opiate testing at the current levels and the potential cost relief represented by the proposed higher cut-off levels for opiates that, when the Commission published the proposed FFD rule revisions, were being proposed by HHS. (HHS has since formally adopted these higher opiate cutoff levels. See 62 FR 51118, September 30, 1997.) It has also carefully considered the potential risk to public health and safety posed by failure to identify opiate abuse. The NRC has determined that the protection of public health and safety necessitates the continued use of the current cut-off levels for opiates. This means that MROs will need to continue evaluating whether the presence of opiates, even if the specimen is not declared by the MRO to be a violation of the licensee's FFD policy, presents a potential safety risk. To eliminate unnecessary confirmatory tests, the NRC will adopt the HHS policy with respect to testing for 6-AM, which is based on the pharmacology of heroin metabolism, i.e., 6-AM is likely to be present only when morphine is present in the specimen and its concentration exceeds 2,000 ng/ml. Testing for 6-AM will be required only when confirmed morphine concentrations exceed 2,000 ng/ml.

Related summary comments and NRC responses may be found at: 4.2.6, 9.3.1, 9.3.2

3.7 NRC Question Seven: Blind Performance Testing

A key element of assuring the integrity of the testing program is the continued assurance of test accuracy through licensees' submission of blind performance test specimens to HHS-certified laboratories as required by section 2.8(e) of Appendix A. The NRC has received a number of suggestions regarding improving these blind performance test specimen requirements. The Commission is considering each of these suggested revisions and invites public comment on the following:

- (a) A limited HHS survey of blind performance test specimens supplied by various vendors has indicated a wide range of drug or metabolite concentrations in spiked specimens. Should the NRC require licensees to assure that concentration ranges for blind performance test specimens be within a defined range (to be determined in consultation with HHS)?

Summary of comments:

Three commenters stated that there is no reason or it is unnecessary for drug or metabolite concentrations in spiked specimens to be within a defined range. One of these commenters also noted that neither the NRC nor DOT regulations define the concentration levels of "spiked" blind performance specimens. The same commenter states that, if they are required to be in a defined range, this requirement must be consistent in all regulations including HHS, DOT, and NRC. Another commenter stated that the purpose of blind performance testing is to determine a laboratory's ability to detect a substance and not to determine concentration levels. This commenter also noted that there are no standards for manufacturing blind samples and that metabolites may adhere to the containers or leach out of the blind sample thus resulting in a lower level of a metabolite being reported. Another commenter stated that licensees should not

establish concentration ranges for blind samples, however if the testing levels differ from HHS levels then it may be appropriate to allow different concentrations in the positive blind samples. The same commenter did not agree with the proposed policy that 10 percent of the blind samples be spiked at 60 percent of the testing level used at the laboratory since the NRC allows licensees to use different testing levels and these samples may be reported as positive or negative and the laboratory may be judged to have reported an incorrect result. (Identification numbers: 7; 10; 14; 20; 25; 32)

NRC response:

The NRC has decided to adopt changes made to the HHS Mandatory Guidelines and establish specific criteria in section 2.8(e) of Appendix A. A specific concentration range (60 to 80 percent of screening cutoff values) is established for 10 percent of the positive blind specimens as a QA/QC measure of the laboratory's ability to determine specimen validity and perform special processing.

In response to inquiries concerning any technical difficulty in manufacturing spiked blind performance specimens within a defined range, leading toxicologists have assured the NRC that vendors that formulate blind specimens should be capable of providing diluted or adulterated specimens spiked to plus or minus 10 percent of any value, whether it is the normal cut-off level or 60 percent of that level.

Related summary comments and NRC responses may be found at: 9.4.1

(b) Should the NRC require that providers of performance test specimens be separate and independent (no conflict of interest) from those performing the specimen collection, specimen testing, MRO, and auditing functions?

Summary of comments:

Three commenters did not agree that providers should be separate and independent. One commenter stated that as long as quality control blind performance specimens are certified by immunoassay and GC/MS testing, the provider does not need to be separate and independent. This commenter also stated that current industry experience indicates that there is no need for further restrictions. However, if audits reveal compromises, this commenter thought that the HHS Mandatory Guidelines would be the appropriate vehicle for such restrictions. Another commenter stated that in the eight years of the HHS program there has not been a conflict of interest situation that has prevented a problem from being reported.

Three commenters agreed that test specimen providers should be separate and independent so as to avoid conflicts of interest. One of these commenters stated that it would ensure that the laboratory does not pre-record results in its reporting system. (Identification numbers: 7; 10; 14; 20; 25; 32)

NRC response:

At this time the NRC is not instituting a requirement that performance test specimen providers be separate and independent from contract providers of other laboratory functions for the licensee. The NRC will, however, continue to monitor the HHS review of the adequacy of the performance test program elements.

Related summary comments and NRC responses may be found at: 4.2.8, 9.4.2, 15.1.7

3.8 NRC Question Eight: Non-Instrumented Screening Devices

The NRC has received requests from several licensees and vendors to permit the on-site use of non-instrumented, qualitative immunoassay methods that involve the use of inexpensive, disposable devices. As discussed in more detail under the proposed changes to section 2.7 of Appendix A, these screening techniques have not been validated to achieve the high levels of specificity and accuracy that are needed in FFD programs. Of concern to the Commission is that these devices may produce an unacceptably high number of false negative test results and may be easily subverted.

(a) The Commission invites public comment on the advisability of creating guidelines, quality assurance procedures, and performance standards to govern use of these devices.

Summary of comments:

Several commenters, responding to the NRC's concern about the specificity, accuracy, and quality control procedures, pointed out the widespread acceptance of such devices in hospital laboratory environments. These commenters suggested that this acceptance shows that the devices are of equal or superior utility to testing laboratories. Otherwise, they would not be used so extensively in clinical settings, which are regulated by CLIA proficiency and validation standards. Other commenters pointed out that all immunoassays are subject to subversion regardless of whether they are on-site, non-instrumented testing devices or laboratory tests. These commenters maintained that many of the existing controls for urine specimen collection and on-site drug testing already address techniques for prevention of subversion of either instrumented or non-instrumented devices. In addition, it was pointed out that many non-instrumented testing devices have internal controls to detect adulteration of samples, which, while not universally effective, do provide additional defensive measures.

Several commenters brought up the fact that clinical testing of non-instrumented testing devices has been conducted and results published in professional journals. Two commenters provided the NRC with results of studies measuring the specificity and accuracy of these devices. These studies appear to indicate that the devices yield results with regard to accuracy, specificity, and the number of false negatives that are comparable to instrumented testing devices. However, some uncertainty was expressed in this regard due to the dearth of validation studies conducted by objective evaluators who are not manufacturers of the devices. (Note: A study conducted for the Administrative Office of the U.S. Courts and completed in early 1997, concluded that false negative results, at least for some of the licensees, is still a problem. See Comment 9.1.1.) Commenters requested guidance as to other sources of validation processes that might be considered suitable for validation of on-site non-instrumented testing devices. One commenter pointed out that, in the absence of a particular Federal agency to perform formal validation studies, the historical practice of relying on third-party sources available in the scientific literature to validate HHS and on-site laboratory methods should also be sufficient to validate non-instrumented testing devices.

Other commenters supported developing industry-sponsored guidance regarding non-instrumented testing devices. They suggested that the Federal Food and Drug Administration, HHS, or the Nuclear Energy Institute could develop such guidance, or that joint guidance could be developed based on discussions between NRC staff and industry representatives. They also recommended that such guidance should address NRC concerns about the devices, such as

quality control, performance standards, use of the devices for screening purposes and identify the most effective implementation methods with regard to developing controls to prevent subversion, confidentiality, and record keeping.

A number of commenters recommended specific quality assurance procedures and performance standards which should be followed if on-site, non-instrumented testing devices are authorized. These included the requirement that the manufacturer's recommended quality assurance procedures be followed; the requirement that, upon the receipt of each lot of the product, a quality test would be conducted using certified positives and a certified negative for each drug on the panel; the prohibition of the use of devices and materials that have past due expiration dates; and the investigation of non-instrumented testing device errors and other matters accomplished in accordance with section 2.8(f) of Appendix A. (Identification numbers: 6; 7; 10; 14; 15; 20; 25; 32; 6010)

NRC response:

The NRC has decided to prohibit the use of non-instrumented screening devices to test for drugs of abuse pending an expected HHS/SAMHSA decision as to whether these devices should be used in Federal workplace testing programs. HHS has been tasked by Congress to review the use of these devices. The Administrative Office of the U.S. Courts is also addressing the onsite use of non-instrumented testing devices and, as noted above, has recently completed an in-depth evaluation of these devices. At this time, it appears that false negative results are still a problem for at least some of these devices. The relevant comments submitted to the NRC on this issue have been forwarded to HHS. The NRC will permit the use of non-instrumented devices in tests to determine the validity of specimens.

Related summary comments and NRC responses may be found at: 9.1.1

(b) Alternatively, should the Commission prohibit the use of these devices until such time as HHS (or another agency) has developed guidelines, procedures, and standards?

Summary of comments:

Some commenters addressed this concern by pointing out that the rule's current requirement that testing devices meet FDA standards addresses this issue, as the FDA reviews the devices for completeness and statistical validity. In addition, several commenters stated that many of the concerns raised by the NRC in the proposed rule are not specific to non-instrumented qualitative immunoassay disposable devices but that they would apply to any currently used screening assay whether instrument based or non-instrument based. If on-site non-instrumented testing devices were authorized by the NRC, the devices would be subject to the same NRC inspection standards, licensee audit requirements, and blind sample testing, etc. as are instrumented immunoassay testing methods.

Another commenter suggested that, if use of on-site non-instrumented testing devices is to be prohibited pending independent validation, then independent evaluation should be applied universally to all testing methods, whether on-site or laboratory. If this universal requirement is applied, then all testing methods, including those instrumented devices currently used, that have not undergone such a specific validation process should be prohibited until such independent validation is obtained.

One commenter agreed with the NRC's concern that the use of non-instrumented testing devices would probably result in a higher rate of false negative results and should not be included in the rule. Another commenter responded that currently there is not sufficient information available for the NRC to allow its licensees to use non-instrumented based on-site tests. However, the majority of commenters expressed their support of non-instrumented testing devices and recommended that the NRC should not prohibit the use of the devices. The commenters described the utility and advantages of on-site non-instrumented testing devices. Advantages included: 1) the immediacy of test results, which in the case of negative results allows the individual to quickly return to work, and in the case of positive results minimizes denial because the tests are performed in the presence of the individual; 2) the safety benefits of being able to quickly identify high risk individuals; 3) the deterrent effect generated by the possibility of a random on-site test that yields immediate results; 4) cost savings due to reduced cost of the tests, immediacy of results, and the elimination of the need for an on-site laboratory; 5) better chain-of-custody procedures because fewer specimens have to be transferred to a testing facility; 6) the ability to use the tests around the clock; 7) the ability for specimen donors to provide specimens on-site rather than having to report to a nearby clinic or hospital; 8) quicker in-processing time of contract workers who have negative pre-access tests and 9) the reduced skill levels required of testing personnel. (Identification numbers: 7; 14; 15; 20; 25; 32; 6010)

NRC response:

At this point, it appears that false negative results, at least for some of the non-instrumented screening devices, are still a problem. Until HHS makes a ruling on the acceptability of these devices in a workplace setting, the NRC will prohibit the use of non-instrumented devices to test for drugs of abuse.

Related summary comments and NRC responses may be found at: 9.1.1

(c) Should there be a Conforming Products List for these devices similar to that published by the National Highway Traffic Safety Administration (NHTSA) for evidential breath measurement devices? Who should administer such a program?

Summary of comments:

Several commenters recommended that a Conforming Products List be developed for on-site non-instrumented testing devices. One commenter recommended that such a list should be developed and that it should include and be applicable to all test methods used in on-site laboratories or in HHS certified laboratories. The commenter suggested that the Conforming Products List could be used as part of a validation program for all testing devices. Another commenter suggested that approval by the FDA of non-instrumented testing devices for commercial distribution precludes the need for a Conforming Products List. The commenter recommended, that if a Conforming Products List is required for public acceptance issues, then administrative delays should be minimized as much as possible, such that new devices are included on the lists as soon as they become available on the market. (Identification numbers: 6; 7; 14; 20)

NRC response:

The NRC will await the HHS/SAMHSA ruling on the use of non-instrumented screening devices before addressing the issue of a Conforming Products List.

Related summary comments and NRC responses may be found at 9.1.1.

3.9 Other Specific NRC Questions

In addition to the eight questions the NRC asked at the beginning of 61 FRN 21105 at 21107 to 21108, additional questions were specified in the general discussion section of this FRN. These questions, a summary of comments received, and the NRC's responses are provided below.

3.9.1 Abuse of Escorted Access

NRC question:

The NRC understands that some contractors have requested escorted access for individuals with a drug history in order to avoid informing the licensee. The Commission desires comments as to whether the rule should be revised so that this practice is no longer permitted....

Summary of comments:

No comments were received in response to this question.

NRC response:

Section 26.23 (a)(2) has been revised to clarify that personnel with a known history of substance abuse will not be assigned duties covered by Part 26 without the knowledge and consent of the licensees.

Related Summary Comments and NRC responses may be found at: None

3.9.2 Data on Overturning BAC Results

NRC question:

...the NRC desires data on the number of times blood specimens have been drawn and any instance where the BAC results were overturned. Approaches licensees have taken to maintain this capability and the associated costs would be useful for evaluation of possible future changes in this requirement...

Summary of comments:

Several commenters provided data regarding the number of times blood specimens were drawn to confirm positive breath alcohol tests. Four of the commenters cited no instances in which a positive breath alcohol test result was overturned due to contradicting blood test results. These four commenters maintained that the blood draw requirement should be eliminated because it is costly and not required under the DOT program. A fifth commenter maintained that the blood draw provision is useful because breathalyzer equipment occasionally may be unreliable, and because blood alcohol test results are more defensible in court than breath alcohol test results. In

support of his argument, this commenter cited two instances in which the results of positive breath alcohol tests were overturned due to negative blood alcohol test results. This commenter also noted two civil litigation cases in which blood alcohol test results provided increased defensibility in court. (Identification numbers: 7, 15, 20, 6010, 6013)

NRC response:

The NRC has carefully evaluated the comments and determined that it is desirable to maintain the requirement that individuals have the option of providing a blood specimen for analysis to provide additional information in the appeal of a positive alcohol test.

Related summary comments and NRC responses may be found at: 10.3.1 and 10.3.5

3.9.3 Management Information System

NRC question:

The NRC also seeks public comment as to whether the NRC should develop a management information system similar to that promulgated by DOT and its operating administrations (58 FR 68194 through 68285; December 23, 1993).

Summary of comments:

One commenter specifically recommended that the NRC not adopt the management information system promulgated by DOT for several reasons. Among the reasons cited were several additional reporting requirements, and the differences between the DOT system's reporting format and the current NRC system's reporting format. (Identification numbers: 36)

NRC response:

At this time, the NRC will not be developing a management information system beyond the reporting requirements of sections 26.71(d) and 26.73.

Related summary comments and NRC responses may be found at: 4.1.7

3.9.4 Program Performance Indicators

NRC question:

The NRC is specifically interested in public comments on program performance indicators in addition to those contained in the text of the proposed amendment to the rule and whether they should be added to the rule or included in a guidance document...

Summary of comments:

One commenter suggested that the NRC follow the railroad industry and require reporting of sufficient information to establish the performance basis for a nuclear industry-wide random testing rate based on historical positive test result percentages. This commenter also recommended that, instead of the proposed amendments for reporting requirements, data collection should be done as needed to support performance-based FFD programs. (Identification numbers: 5001)

NRC response:

The NRC is exploring the potential utility, feasibility, and relative costs and benefits of FFD program performance indicators. Some of the potential uses being examined are the ability of performance indicators to help evaluate the FFD rule and its requirements, assess licensee programs, determine where to focus regulatory inspections, provide a basis for licensees to determine self-audit needs, and promote a more performance-based approach to FFD regulation. The NRC is addressing how different types of performance information can be best combined to create an effective and efficient approach to FFD program evaluation and regulation. The NRC expects to have a report on FFD program performance indicators available by mid 1999.

Related summary comments and NRC responses may be found at: 17.2.6 and 17.2.9

3.9.5 Data on Specimen Degradation

NRC question:

The NRC specifically invites comments regarding the proposed revisions concerning specimen degradation and whether rule changes should be made or the information published in report form for voluntary use. In particular, the NRC is interested in data that licensees conducting on-site testing could provide. Of specific interest would be examples of on-site unconfirmed positives that had degraded during shipment. Licensees or other parties submitting such information should include any known factors, such as temperatures and duration of exposure to the suspect condition, that may have contributed to the problem...

Summary of comments:

No comments were received in response to the NRC's request for data regarding on-site unconfirmed positives that had degraded during shipment. However, some licensees provided data during the development of the proposed amendments.

NRC response:

The NRC thanks those licensees who voluntarily provided data on this issue prior to publication of the proposed revisions, some based upon informal experiments. As described in the May 1996 Federal Register notice at 91 FR 21122, data and reports from licensees supported the NRC's pilot tests to gain insight on the nature and extent of the specimen degradation problem. The NRC anticipates no further action at this time, beyond the current revisions addressing this issue.

Related summary comments and NRC responses may be found at: None

3.9.6 Comments to OMB on Collection of Information

NRC question:

The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the collection of information contained in the proposed rule. Comments to the OMB on the collection of information or on the following issues must have been submitted by June 10, 1996. 1) Is the proposed collection of information necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility? 2) Is the burden estimate correct? 3) Is there a way to enhance the quality, utility, and clarity of the information to be

collected? 4) How can the burden of the information collection be minimized, including the use of automated collection techniques? Send comments regarding these burden estimates or any other aspect of this collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch.

Summary of comments:

One commenter stated that the information collected in the semi-annual Performance Data Report is not necessary for the NRC to perform its 10 CFR Part 26 functions, and maintained that, "the assurance that personnel are not under the influence of any substance or mentally or physically impaired" is not enhanced by the reporting of information. This commenter also noted that some burdens may be underestimated (e.g., an estimate of 15 minutes per telephone call may be accurate, but the estimate does not include the one hour of preparation time necessary to compile and evaluate event information, inform management, and coordinate the call with licensing personnel). Also, the commenter recommended that the reporting requirements be amended as follows: 1) report only information required to support performance-based FFD programs; 2) report information on an annual basis; 3) allow utilities the option to submit either one consolidated report, or individual site reports, and; 4) report contractor/vendor personnel as only one category, rather than either "long-term" or "short-term". This commenter also suggested that the NRC establish an electronic mail system for submitting necessary information. (Identification numbers: 5001)

NRC response:

The NRC finds the information collected in the Summary of FFD Performance Report necessary and useful. The NRC requires program performance data to evaluate the ongoing success of the program and to identify program weaknesses. The analysis provided in the annual program performance summary report is intended to allow the NRC and licensees to evaluate any individual FFD program relative to industry-wide program performance. In addition, many licensees include lessons learned, which have been included in the NRC's annual summary reports. Some licensees have indicated they find the reports and the NRC's annual summary reports useful for these purposes.

In reference to the suggestion that the NRC only collect information required to support performance-based FFD programs, the NRC concurs that routine data collection and analysis is the heart of any performance-based program. Increased emphasis on performance focused programs will increase requirements for additional routine, ongoing data collection, of the types of data discussed in the NRC's May 1996 Federal Register notice. The NRC is continuing to consider the desirability of collecting additional data for these purposes.

Although the NRC did include some time for internal coordination, it did not include sufficient time for all the internal coordination or documentation described by the commenter. However, this difference should not impact the cost estimates for this rule revision, because it is a clarification of existing requirements and should not result in additional costs. Furthermore, the overall impact of the reporting requirements should be low, as the total number of significant FFD events has been low (an average of 37 per year for the past 3 years).

The NRC concurs that reporting of program performance data should be on an annual basis, and has revised the reporting requirements of section 26.71(d) accordingly. The NRC disagrees with the contention that utilities should be permitted to submit a consolidated report. The NRC uses information reported from each site for a number of purposes. In addition to being used to

produce the annual summary report, data from program performance reports are used to track performance over time of each site, to note unusual performance over time at each site, and to identify site specific issues for follow up. These various purposes preclude the reporting of results at the utility level.

With regard to the reporting of long- and short-term contractors, the rule does not specifically require separate reporting of test results for long-term and short-term contractors. The NRC will discuss changes in the standard reporting form with NEI, including whether the separation of long- and short-term contractors will continue. Finally, the NRC has no objection to NEI or other industry group creating an electronic mail system acceptable to the NRC for submitting information when the data collection format is revised in response to the FFD rule revisions. The NRC will be discussing changes to the program performance reporting form, which was developed by NEI, to address changes required by the revisions to the rule. This and other comments will be considered in those discussions. The NRC will continue to capitalize on information technology for improving information access, information distribution, and public interaction. However, the NRC will not eliminate paper in favor of electronic communication without full consideration of the public's ability to access information electronically.

Related summary comments and NRC responses may be found at: 17.2.1; 17.2.3; 17.2.6; 17.2.7; 17.2.10; and 17.2.13.

4.0 Guidelines for FFD Programs

Several commenters discussed the relationship of the NRC's rule and proposed revisions with other Federal programs. In particular, many commenters addressed the NRC's integration of many of the Department of Health and Human Services (HHS) guidelines. Several comments focused on more general context issues of the proposed rule revision, such as the prescriptiveness of the rule, the NRC's experience in workplace drug and alcohol testing programs, and the program's effectiveness.

4.1 Relationship to Other Federal Programs

Several commenters addressed the relationship between the NRC's FFD program and other Federal workplace drug testing programs. For example, a number of commenters approved of the NRC's proposed revisions that create consistency with other Federal programs. Some commenters said that there should be even greater consistency across programs, particularly regarding the technical aspects of drug testing, while others mentioned that certain aspects of other testing programs should not be duplicated. Other commenters raised specific questions regarding the NRC's criteria for acceptance of other programs.

4.1.1 Relationship to Other Federal Programs: Relief from Double Coverage

Comment:

A number of commenters expressed appreciation of the NRC's attempt to provide relief from the "double coverage" of individuals who are covered by multiple Federal workplace drug testing programs. Commenters stated that other programs should reciprocate. (Identification numbers: 5; 12; 6019)

Response:

The NRC concurs with these comments and will continue to look for opportunities to reduce the burden of workplace drug testing programs without jeopardizing public safety.

4.1.2 Relationship to Other Federal Programs: General Performance Objectives

Comment:

Several commenters noted that the NRC's criterion for acceptance of other programs — meeting the "general performance objectives" of the NRC's program — was too vague and needed clarification. (Identification numbers: 7; 10; 20; 5002; 6011)

Response:

The NRC acknowledges that the term "general performance objectives," which was intended to provide broad flexibility, was vague. The reference to general performance requirements has been replaced with more specific language. All elements listed in sections 26.20 to 26.73 of Part 26 must be covered. Specific criteria must be met under section 26.24, Chemical and Alcohol Testing. Acceptable program elements are limited to those under Federal agency or State regulation. Chemical and alcohol testing requirements must include requirements for preaccess, for cause, and random testing for marijuana, cocaine, opiates, phencyclidine, amphetamines, and

alcohol at or below NRC mandated cut-off levels; and use of certified laboratories for urine testing. In addition, appeal rights must be provided in a fair and impartial manner. If an employee is covered by a program that is deficient in one or more of the NRC program elements, the licensee can supplement that program to achieve the overall FFD requirements. If there are conflicting standards, the NRC will accept the more stringent requirement.

4.1.3 Relationship to Other Federal Programs: Random Testing Rate

Comment:

One commenter asked whether an individual tested at a 25% random rate under another program would satisfy the general performance objectives of the NRC's program. (Identification numbers: 5002)

Response:

A person covered by a 25% random test rate mandated by another Federal program (assuming the required elements are present) would be acceptable under the flexibility that the NRC will permit under this revision to the rule.

4.1.4 Relationship to Other Federal Programs: Alcohol Testing

Comment:

Another commenter asked whether a DOT preaccess test (which does not include alcohol) would qualify as a preaccess test in the NRC program. (Identification numbers: 6011)

Response:

The DOT program requires urine testing for the five drugs listed in the HHS mandatory guidelines at or below NRC cut-off levels and requires use of an HHS-certified laboratory, hence, the urine test for drugs would be accepted. However, an alcohol test under the NRC program would need to be administered in addition to the urine testing for drugs in the DOT preaccess test.

4.1.5 Relationship to Other Federal Programs: Program Variation

Comment:

One commenter stated that the differences between NRC and DOT programs were so great that no reference should be given to DOT's requirements. Another commenter stated that unless the NRC adopts DOT's and HHS's requirements without changing them, licensees would be unlikely to implement this flexibility because it would mean that employees in similar positions might be tested under different policies and procedures. (Identification numbers: 23; 25)

Response:

The NRC acknowledges that there may be potential difficulties with implementing this provision but nevertheless desires to provide for increased coordination across Federal programs. While the NRC would prefer to direct licensees to use the most stringent requirements, it is aware that this would not satisfy the more prescriptive but less stringent requirements of other Federal agency or State programs, and therefore, not provide the desired relief from redundant testing. Hence, the

NRC has provided guidance that should result in adequate coverage of individuals and provide some relief to individuals currently being tested under multiple programs. As noted in the response to Summary Comment 4.1.2, the NRC has added some specificity that may improve the practicality of implementing this provision.

4.1.6 Relationship to Other Federal Programs: Technical Consistency

Comment:

One commenter stated that guidance regarding the technical aspects of drug testing should be consistent across programs. For example, if a beaker of sand was sent to an HHS laboratory it would be reported as negative (in accordance with HHS mandatory guidelines), unsuitable for testing (in accordance with DOT guidelines), and unable to determine the validity of the specimen (under NRC guidelines). Although the report that the container was full of sand is more likely under the DOT or NRC program, it is not guaranteed. (Identification number: 8)

Response:

The NRC appreciates the comment and has referred it to HHS. The NRC has no regulatory authority over DOT or HHS.

4.1.7 Relationship to Other Federal Programs: Consistency of Requirements

Comment:

Several commenters stated that certain aspects of other Federal drug testing programs should or should not be duplicated by the NRC. Definitions of drug test results, the 50 ng/mL cut-off for THC, alcohol testing processes (e.g., no second confirmatory testing device), and HHS revisions were among the aspects of other programs the NRC was urged to adopt. Examples of policies that were mentioned as undesirable to adopt were the DOT's management information system requirements. (Identification numbers: 9; 10; 36; 6005)

Response:

The NRC has carefully considered these suggestions and has, in some cases, revised certain sections of the rule accordingly. The NRC has incorporated many of the changes made to the HHS Mandatory Guidelines and made other revisions to create consistency with the DOT Procedures for Workplace Drug Testing when those revisions would support the performance goals of the NRC's program. The NRC has a very substantial safety interest in the FFD rule's general performance objectives of complete removal of drugs and alcohol and their effects from nuclear power plants. This differs somewhat from the demand reduction emphasis of the HHS and, to some extent, from the DOT programs.

4.1.8 Relationship to Other Federal Programs: Differences in NRC and DOT Programs

Comment:

One commenter noted that although the NRC's and DOT's FFD programs are often compared, there are significant differences between the philosophy, goals, and mandates of the NRC's FFD program and those of DOT's FFD program that reflect significant differences in the industries they regulate. (Identification number: 5003)

Response:

The NRC agrees, and is well aware of these differences. In the interest of reducing inconsistencies across programs, The NRC has endeavored to be compatible with DOT's standards when those standards are consistent with NRC goals.

4.2 HHS Changes and Related Issues

A number of commenters responded to the request for comments regarding whether the NRC should incorporate revisions HHS made to its Mandatory Guidelines for Federal Workplace Drug Testing Programs in June, 1994. In general, while there was support for revising the regulation to respond to those HHS guideline changes, there was also some disagreement regarding whether the HHS revisions should be accepted "as is" or with adjustments to respond to the specific safety requirements of the nuclear industry. In addition, this section responds to comments regarding other HHS related issues.

4.2.1 HHS Changes and Related Issues: Adapting HHS Guidelines to the Nuclear Industry

Comment:

Several commenters agreed that the NRC should adopt appropriate revisions to the HHS Guidelines. One commenter noted that some of these proposed revisions were appropriate but that the NRC should incorporate modifications to other HHS Guidelines. This response was consistent with that of another commenter who suggested that the NRC incorporate the HHS Guidelines revisions, but continue to allow licensees the flexibility to do on-site testing, use lower cut-off levels, and make other appropriate adjustments. (Identification numbers: 3; 7; 14; 20; 30; 32)

Response:

The NRC concurs with the commenters' view of the value of a general acceptance of the HHS Guidelines revisions, and the need to make adjustments to some of those revisions to respond to the safety requirements specific to the nuclear industry.

4.2.2 HHS Changes and Related Issues: Lack of Consistency with HHS Guidelines

Comment:

One commenter noted that the NRC's FFD program contains a number of policies and procedures that are different from HHS' program and recommended that the NRC refrain from stating its intent to be consistent with the HHS Guidelines. In order to reduce confusion, the commenter further recommended that the NRC simply refer to those parts of the HHS Guidelines it wants to accept. Another commenter recommended that the changes in Appendix A of Part 26 should replicate the HHS Guidelines exactly. This commenter also suggested that the adoption of the HHS Guidelines should be made automatic in Part 26 so that, as the HHS Guidelines change, the NRC's FFD rule will remain consistent with them. (Identification numbers: 10; 25)

Response:

The NRC believes that consistency across Federal programs is desirable when practicable. However, the NRC concludes that some program differences are necessary, primarily because it desires to continue permitting licensees to implement more stringent programs, set lower cutoff levels, test for additional drugs, and conduct on-site testing. While much of the HHS Guidelines has been adopted as published by HHS, the NRC has made some modifications to achieve compatibility with the Commission's original goals in publishing the FFD rule. Adoption of a procedure that would automatically incorporate HHS Guideline changes would not allow the consideration of issues specific to the nuclear industry. See also response to Summary Comment 4.2.3.

4.2.3 HHS Changes and Related Issues: Adopting HHS Guidelines by Reference

Comment:

One commenter suggested that the sections of the rule that simply repeat provisions in the HHS Guidelines should be deleted and the HHS Guidelines simply referenced. (Identification number: 25)

Response:

The NRC considered adopting HHS Guidelines in total by reference during the initial rulemaking process which culminated in 1989. A number of comments were received at that time and summarized in NUREG 1354. Numerous commenters stated that the NRC should not adopt the HHS Guidelines in their entirety. The commenters indicated that no other source of guidance for urine testing provides methods that are as rigorous for ensuring chain-of-custody protection for urine specimens and laboratory quality control. However, commenters noted that the HHS Guidelines were developed for Federal agencies rather than nuclear power plant testing programs and so are inappropriate in several respects. Commenters pointed out that the HHS Guidelines: (1) inappropriately limit the number of drugs for which testing can be performed; (2) prescribe cut-off levels for testing that are higher than those currently used in many industry programs; (3) refer to decisions by the Secretary of the Department of Health and Human Services that would be difficult for licensees to obtain; (4) discuss the Privacy Act and Public Law 100-71 which do not pertain to workers in privately-owned nuclear power plants; (5) may be changed by the HHS in ways that conflict with the NRC's needs; and (6) do not allow licensees to perform initial screening tests. Also at that time, one commenter stated that the HHS Guidelines are oriented toward rehabilitation of individuals with positive test results rather than toward ensuring public health and safety. Another commenter noted that because the HHS Guidelines are not directly relevant to nuclear power plant programs, licensees would be required to interpret which aspects of the Guidelines apply to their fitness-for-duty programs, with the result that licensee programs and enforcement actions could differ significantly across the industry. The commenters proposed that the NRC should use the HHS Guidelines as a basis for developing NRC Guidelines that are appropriate for the nuclear power industry. In response to commenters' concerns, the NRC developed its own Guidelines, published as Appendix A to the final rule, which are an adaptation of the HHS Guidelines. The NRC cannot require, by reference, its licensees to meet selected HHS requirements, nor permit change without undergoing NRC's public comment and review processes.

4.2.4 HHS Changes and Related Issues: Time Period for HHS Laboratory to Report Results

Comment:

Two commenters objected to the proposed reduction from the 5 to 4 working day time frame within which HHS-certified laboratory test results must be reported to the MRO. The commenters maintained that since both HHS and DOT allow results to be reported within five working days, the NRC should also continue to allow five working days in order to avoid the inadvertent non-compliance of an HHS-certified laboratory. (Identification numbers: 10; 6005)

Response:

The NRC agrees with the commenters' suggestion. The five working day reporting time frame will remain in order to create consistency across Federal programs and avoid inadvertent non-compliance. Also see Summary Comment 9.5.2.

4.2.5 HHS Changes and Related Issues: Temperature

Comment:

A number of commenters addressed the temperature range required by HHS and that required by NRC. These comments are summarized in other, relevant sections.

Response:

These comments are discussed in more detail and responses are provided in Summary Comment Section 11.3.

4.2.6 HHS Changes and Related Issues: Cut-Off Levels and Tests for Adulterants

Comment:

A number of commenters responded to the NRC's request for comment on proposed changes regarding opiate cut-off levels, 6-AM testing procedures, the adoption of lower cut-off levels for THC, and testing for adulterant/masking agents, changes which have been proposed by HHS. The commenters' responses to the proposed changes are addressed in more detail in other, relevant sections. (Identification numbers: 7; 9; 20)

Response:

The NRC appreciates commenters' responses to these specific issues. Please see Summary Comments 9.3.1, 9.3.2, 9.3.3, 9.3.5, and 11.4.1 for specific NRC responses to each issue.

4.2.7 HHS Changes and Related Issues: 6-AM Testing

Comment:

One commenter recommended that the current requirements for 6-AM testing should remain as is, pending any action taken by HHS on opiate testing. (Identification number: 20)

Response:

The NRC concurs that current requirements should stand with the exception that 6-AM testing is required only when the confirmation test shows a morphine concentration exceeding 2000 ng/ml. The NRC will continue to review HHS' actions on the matter. See Summary Comments 9.3.1 and 9.3.1 and 9.3.2.

4.2.8 HHS Changes and Related Issues: Independent Providers

Comment:

One commenter noted that, as long as blind performance specimens are certified by immunoassay and GC/MS testing, there is no reason for the provider to be separate and independent from contract providers of other laboratory functions for the licensee. The commenter noted that the HHS Guidelines are the appropriate place for such requirements. (Identification number: 7)

Response:

At this time, the NRC is not proposing to require that performance test (PT) specimen providers be separate and independent from contract providers of other laboratory functions for the licensee. The NRC will, however, continue to monitor the HHS review of the adequacy of the PT program elements. Also see Summary Comment 9.4.2.

4.2.9 HHS Changes and Related Issues: Adulteration Testing

Comment:

One commenter noted that if adulteration becomes an issue of major significance such that testing is mandated, HHS should impose the testing requirement, not the NRC. Another commenter agreed, and also contended that testing for adulterants and masking agents should be required. (Identification numbers: 7; 20)

Response:

Prior to the publication of the rule package, HHS allowed, but did not require HHS-certified laboratories to test for adulteration and dilution. Subsequent to the publication of the proposed rule package, HHS published a notice regarding adulteration and dilution testing to HHS-certified and applicant laboratories (NLCP Program Document #35). This document establishes recommended guidance for HHS-certified laboratories that choose to test for adulteration and dilution--including standards for levels of creatinine (and specific gravity (SG) under some conditions), pH, and nitrites. The standards constitute a policy for conducting, reporting, and interpreting drug and adulteration test results for specimens tested under federally regulated workplace drug testing programs. These changes were motivated by the reports to HHS that the number of adulterated/diluted specimens has increased. In response to these new HHS standards, the NRC has adapted this section to achieve more consistency with the new HHS policy.

4.3 General Context Issues

Several commenters addressed the level of prescriptiveness of the regulation, with comments ranging from requests for more specific guidance to recommendations for increased flexibility. Other commenters noted the breadth of program experience that the NRC has gained over the past several years of program administration.

4.3.1 General Context Issues: NEI Comments

Comment:

A number of commenters supported in whole or in part NEI's comments on the proposed rule package. (Identification numbers: 4; 15; 16; 19; 21; 22; 23; 24; 27; 29; 31; 32; 34; 36)

Response:

The NRC appreciates the time and effort expended by NEI and its members to carefully review and provide detailed comments on the proposed revisions to 10 CFR Part 26. Responses to these comments are provided in appropriate categories throughout this document. A complete list of all summary comments that reflect NEI comments is provided in Appendix B, Alphabetical List for Comment Letters under Beedle, Ralph E., NEI.

4.3.2 General Context Issues: Level of Regulatory Prescriptiveness

Comment:

There were differing opinions regarding the level of prescriptiveness of the regulation. While one commenter suggested that more detail was needed to assure that licensees are not subject to arbitrary standards, another commenter stated that the rule revisions were counter to the NRC's mandate to establish standards by which to judge practices rather than the practices themselves. One commenter was concerned that the use of flexibility and common sense as allowed by the rule in some instances may cause problems if the NRC interprets a situation differently than the licensee does. Another commenter noted that the flexibility provided in the NRC's rule has resulted in some of the best run FFD programs in the country. (Identification numbers: 7; 5003; 6006)

Response:

The NRC has striven to achieve balance between 1) the need for prescriptiveness to establish clear requirements as a legal basis for the implementation of certain aspects of the program and 2) the desirability of flexibility in rule implementation. The NRC will continue to work to provide appropriate flexibility to licensees.

4.3.3 General Context Issues: Program Effectiveness

Comment:

One commenter suggested that the NRC has proposed to increase scrutiny of both utilities and employees in response to the program's low number of positives. The commenter advised the NRC to acknowledge the program's effectiveness, rather than increase requirements. (Identification number: 28)

Response:

The NRC recognizes that licensee programs have been generally successful but believes that it must continue to review results and adjust requirements based on program performance. It is important to recognize that the environment in which the program functions is not static. Changes in conditions such as drug availability and methods of subversion require programmatic response.

Furthermore, the NRC appreciates the commenter's assessment of the overall success of its FFD program. However, the NRC believes that some contribution to the low number of positives may be attributed to subversion. The safety of the public requires ongoing improvements to assure the program's continued effectiveness.

4.3.4 General Context Issues: NRC Experience with FFD Program

Comment:

One commenter noted that the NRC has gained a great deal of experience and insight into drug and alcohol testing because of its inspection programs, commissioned research and literature reviews, required performance audits, and the cooperation and professionalism of the industry FFD administrators. Thus, the NRC has a good deal of hard data to support its actions and contentions. (Identification number: 5003)

Response:

The NRC agrees that the collection and evaluation of information on the experience of workplace drug testing programs and that being aware of the issues and technical developments related to fitness-for-duty programs is essential to assure the effectiveness of these programs.

5.0 Scope of the Rule

Several commenters raised issues regarding the scope of the rule. These included the rule's general applicability, its applicability to certain areas of nuclear facilities (protected areas versus vital areas), and its applicability to particular types of workers, particularly FFD personnel. In addition, implementation guidance regarding the rule's coverage of certain workers was requested.

5.1 General Issues

One commenter asked if the NRC is considering prior input on the proper scope of the rule separately from input on the current proposed revisions to the rule and another commenter recommended that the FFD rule cover only those individuals with access to vital areas.

5.1.1 General Applicability

Comment:

One commenter asked whether the NRC's consideration of the proper scope of the rule following its 1994 request for information on this issue is being handled separately from these proposed revisions to the rule. (Identification numbers: 6016)

Response:

This issue of whether certain categories of workers, such as secretaries, should be excluded from random testing is being addressed independent of this rulemaking.

5.1.2 Limiting Scope to the Vital Area

Comment:

One commenter recommended that only people with access to vital areas of nuclear facilities be covered by the FFD rule. (Identification number: 17)

Response:

This issue is being addressed as a separate regulatory action.

5.2 Including FFD Personnel in Testing

Several commenters took exception to the proposed inclusion of FFD personnel in the FFD testing process. Concerns were raised about the effect of the revision on issues of confidentiality and the logistical problems associated with actually testing these personnel. Other commenters supported the proposed revision.

5.2.1 Scope of FFD Personnel to be Tested

Comment:

Several commenters took exception to subjecting some FFD program personnel to Part 26 requirements. Some commenters suggested, for example, that employee assistance program personnel and/or MROs should not be covered by Part 26 because they do not have access to the areas or materials described in § 26.2(a) and many are offsite contract employees. Others argued that the rule should be applicable only to those FFD personnel who make decisions regarding testing. Questions about who will test the FFD program staff were also raised.

Response:

The NRC has revised § 26.2 to clarify its original intent that the specified classes of personnel who administer FFD programs must be covered by Part 26 even though they may work outside the plant protected area. The NRC continues to believe, and industry experience indicates, that FFD program personnel must meet the highest standards of honesty, integrity, reliability, and trustworthiness. While some of these people may not work in protected areas, they do make important decisions regarding the testing of employees who have access to protected areas and perform duties with direct implications for public health and safety. FFD programs must be able to ensure that program personnel do not make errors of omission or commission that can jeopardize program integrity and effectiveness. To clearly identify those individuals whose FFD program responsibilities require that they be tested, the NRC has modified the changes to § 26.2 as proposed (i) to limit the applicability of the linking of test results to those FFD program personnel who can link test results with the person who was tested prior to determination of a FFD policy violation, (ii) to eliminate those making removal and return-to-work recommendations as opposed to decisions, and (iii) to add those making medical and management determinations of fitness.

The NRC recognizes that the requirement that FFD program personnel shall be tested to the extent practicable by people who are independent of the administration of the FFD program may be difficult to meet in some instances. The NRC does not expect licensees to take impractical measures and a reasonable approach is sufficient to comply with this requirement.

The NRC also notes that it is still considering the proper scope of the rule following its 1994 request for information on whether certain categories of workers, such as secretaries, should be excluded from random testing. That issue is being addressed independent of this rulemaking.

5.2.2 Policies and Procedures for Testing FFD Personnel

Comment:

A number of commenters asked questions or provided suggestions regarding the testing or background checks on FFD personnel. These included questions regarding who would test the FFD staff and whether FFD staff should still be required to undergo periodic psychological evaluations when they, like other staff, would be subject to behavioral observation. It was noted that other staff are not required to have periodic background investigations. A number of questions about how to deal with the testing of FFD personnel were also raised. For example, one commenter asked the meaning of “to the extent practicable” in the context of independent testers of FFD personnel. Another commenter asked whether licensee programs need to have a second MRO under contract to test the first MRO. (Identification numbers: 1; 7; 20; 30; 32; 5002; 6004; 6005; 6006; 6023)

Response:

Most licensees have been testing FFD program personnel using personnel from other sites or corporate headquarters to do selection, notification, and collection; this shall continue to be an acceptable practice. Also, licensees may choose to make available the services of an independent provider/collector. The flexibility provided with the term “to the extent practicable” will address occasions when using other personnel outside the FFD program is not practical. Commenters suggested that having two individuals involved in testing would be a reasonable accommodation when an independent collection person is not available. While this practice would be appropriate when using an independent collector is impractical, this would be expected to be an alternative for unusual circumstances rather than a routine practice. Any personnel outside the FFD program used for these purposes must be trained in their duties, as required by section 2.1(d) of Appendix A.

5.2.3 Appeals Board Exemption

Comment:

Several commenters agreed with the proposed changes to include FFD program personnel under the scope of the rule. However, one commenter would like to exempt the members of licensees' appeals boards who hear employee appeals of FFD policy violations. (Identification numbers: 10; 32)

Response:

The NRC concurs and always intended that FFD program personnel be included in the scope of the regulation. The appeals board is required by section 26.28 not to be associated with the administration of the FFD program and, hence, need not be tested as FFD program personnel.

5.2.4 Other Comments on the Inclusion of FFD Personnel in Testing

Comment:

One commenter stated that there is no similar requirement to test FFD personnel in either of the HHS Guidelines or the Department of Transportation Procedures for Transportation Workplace Drug Testing Programs. Another suggested that the regulation of medical agencies does not fall within the purview of the NRC. (Identification numbers: 36; 6006)

Response:

The nature of the nuclear industry makes it both possible and desirable to include FFD personnel in the testing program. The NRC is not testing nor regulating the qualifications of doctors, only assuring that MROs who work in NRC-regulated FFD programs are trustworthy, reliable, and do not abuse drugs or alcohol.

5.3 Other Issues Related to the Scope of the Rule

Some commenters requested specific guidance about how the rule is to be applied to certain types of workers.

5.3.1 Status of State On-Site Inspectors

Comment:

One commenter noted that the changes to the rule, especially with regard to behavioral observation and supervisory duties, do not take into account the state on-site inspectors who are covered by the rule but not subject to the licensees' supervision. (Identification number: 26)

Response:

It is the NRC's understanding that all state inspectors are either subject to licensees' programs, or subject to a state's program that is similar to that required by Part 26. This rulemaking, under section 26.2(f), provides further accommodation. Anyone suspected of not being fit for duty must be denied unescorted access. In the case of state inspectors, the State agency should immediately be informed of any such action.

5.3.2 Multiple Site Access Issues

Comment:

A commenter requested guidance as to whether employees who are badged at multiple sites are to be covered by multiple programs and whether test results can be shared? (Identification number: 5002)

Response:

A worker need be covered under only one program. The licensee should make accommodations to assure testing when a worker is selected or as soon as possible after selection.

6.0 Definitions

Several comments were received about the definitions proposed in the rule revision. Many commenters provided specific suggestions as to how to revise the definitions. A number of commenters suggested that the definitions be changed to be consistent with HHS and DOT definitions. Other commenters asked for further clarification of meaning for some definitions. In particular, a number of comments were received regarding the definitions of “medical determination of fitness,” “confirmed positive,” “laboratory confirmed positive,” and “confirmatory test.”

6.1 Definitions — Legal Drugs

Commenters noted undesired implications or asked for clarification regarding the “legal or employment actions against an individual” part of the “abuse of legal drugs” definition.

6.1.1 Abuse of Legal Drugs

Comment:

Commenters disagreed with the implication in the definition of “abuse of legal drugs” that “legal or employment actions against an individual for use of legal drugs constitute evidence of the existence of a health or safety hazard.” In the view of one of these commenters, the rule should allow MROs to use their medical judgment to make these determinations. (Identification numbers: 7; 20)

Response:

The NRC agrees with these commenters. The wording for this definition has been edited to omit the term “a health or safety hazard” and to replace it with “the abuse of legal drugs.” The NRC believes that legal or employment actions as a consequence of legal drug use are presumptive of the abuse of legal drugs.

6.1.2 Legal or Employment Actions for Abuse of Legal Drugs

Comment:

One commenter asked what “legal or employment actions against an individual” means as it pertains to the definition of “abuse of legal drugs”? (Identification number: 5002)

Response:

Examples of legal actions would include a conviction for driving when under the influence of drugs or alcohol and convictions for sale, possession, or use of illegal drugs. Examples of employment actions would include reprimands or termination due to alcohol or the use of prescription or over-the-counter drugs in violation of company policy.

6.2 Definitions — Medical Determination of Fitness

Commenters recommended that the proposed definition of “medical determination of fitness” should not include the MRO’s administrative and managerial responsibilities and that the definition should be revised to specify that a health care professional may make the determination.

6.2.1 Medical Determination of Fitness: Defining MRO Responsibilities

Comment:

Commenters recommended that the proposed amendment to the definition of “medical determination of fitness” should be simplified to convey the reality of what the MRO should be responsible to determine—reasonable assurance that individuals are medically fit to perform safely and reliably inside the protected area of a nuclear power plant—and not the numerous administrative and management decisions that have been added to the MRO’s purview and are spread throughout the revised rule. One commenter asked if the “medical determination of fitness” is a new concept in the industry. See also Summary Comments 15.1.3 and 15.1.4. (Identification numbers: 7; 36; 5002)

Response:

MROs have always been responsible for understanding the administrative and management areas relevant to their duties. The medical determination of fitness may be done by any qualified licensed physician who may be an MRO. The clarification of what constitutes a medical determination of fitness is not a new concept and does not change the MRO’s relevant duties.

6.2.2 Medical Determination of Fitness: Using Other Health Care Professionals

Comment:

Two commenters suggested that the proposed definition for “medical determination of fitness” should be revised so that a health care professional other than an MRO would be permitted to determine individual worker fitness. Specification of the MRO for this evaluation could lead to issues of lack of MRO availability as a result of the position’s increased responsibilities. (Identification numbers: 29; 32)

Response:

The Commission has always recognized, as discussed when the FFD rule was originally adopted in 1989, that considerable expertise is required for such determinations. The NRC continues to believe that, although some individuals with medical backgrounds who are not licensed physicians may have the appropriate expertise to make medical determinations of fitness, considerations of safety and program integrity require that licensed physicians, who need not be an MRO, continue to make these determinations. See also Summary Comments 15.1.3 and 15.1.4.

6.3 Definitions — Chemical Testing

Two commenters suggested that various chemical testing related definitions be amended to coincide with the HHS and DOT definitions, other commenters provided their suggestions for revisions of specific definitions, and others noted issues that arise with respect to some of the

definitions as proposed. The terms of interest are given in the titles of each of the subsections that follow.

6.3.1 Confirmatory Test, Confirmed Positive, Laboratory Confirmed Positives and Verified Positives

Comment:

Commenters suggested that the “confirmatory test,” “confirmed positive,” “laboratory confirmed positive,” and “verified positive” definitions should be amended to match the HHS and DOT definitions. The confirmatory test would be the second analytic test done by the HHS-certified laboratory, the results the laboratory gives to the MRO would be the confirmed test, and the verified test would be the name for the test once the MRO has made a judgment as to whether the test result constitutes evidence of a violation of FFD policy. (Identification numbers: 10; 6005)

Response:

These suggestions illustrate the need to clearly define these terms to reduce the difficulties in administering testing programs. Based on a review of definitions provided by HHS and DOT, the NRC has concluded it has attained appropriate consistency with those Departments' definitions. Differences in program elements, policies, and procedures make it necessary to provide definitions specific to Part 26.

HHS and DOT use, but do not formally define, terms such as “confirmed positive,” “laboratory confirmed positive,” “verified positive,” “confirmed test,” and “verified test.” Thus the meaning of these terms can only be assumed from their usage. The NRC makes no attempt to define these terms to coincide with the HHS and DOT usage of them since it is impossible to know what is meant exactly in the HHS and DOT contexts and in some instances the assumed meanings would not apply in the NRC context. For example, in the NRC context, MRO evaluation of a positive confirmatory test result for alcohol is not necessary for a verification of a confirmed positive test for alcohol. Thus a term like “verified test” (by the MRO) would not apply for alcohol testing.

The HHS, DOT and NRC definitions for “confirmatory test” essentially coincide with respect to urine specimens. The HHS definition for “confirmatory test” does not address alcohol and the DOT definition with respect to alcohol is stated differently from the NRC definition, although both definitions discuss a second, analytical procedure.

The NRC has deleted the proposed term “unconfirmed positive test result” and replaced it with the term “presumptive positive screening test result” to eliminate some potential for confusion.

6.3.2 Confirmed Positive Test

Comment:

A commenter suggested that the definition for “confirmed positive test” include the statement that someone with a confirmed positive test should not be eligible for unescorted access at any plant unless the test is determined negative by the MRO or the individual meets the requirements for return to service. (Identification number: 7)

Response:

It is inappropriate to include policy statements in definitions. Also see Summary Comment 6.3.4.

6.3.3 Confirmatory Test

Comment:

A commenter suggested that the definition for “confirmatory test” be revised to clarify that, for alcohol testing, a confirmation test would be the second test, following a test with a result of 0.02 percent BAC or greater on an instrument that provides quantitative data of alcohol concentration. The commenter recommended a similar revision to the alcohol testing procedures in section 2.4(g)(18) of Appendix A. (Identification number: 36)

Response:

The NRC believes that the current definition is adequate and appropriate; section 26.24(h) and section 2.4(g)(18) of Appendix A describe the testing procedures and parameters. Appendix A requires the use of specific alcohol testing devices and defines cut-off levels. It is not necessary to include these in the definition. It should be noted that confirmatory tests for alcohol would be tests of the third and fourth breath specimens on a second breath alcohol measuring device. For related issues, see 10.1.2.

6.3.4 Laboratory Confirmed Positive

Comment:

One commenter stated that the proposed amended definition for “laboratory confirmed positive” does not account for those situations in which a laboratory confirmed positive test result can not be verified as a violation of FFD policy by MRO evaluation because of the unavailability of the individual. (Identification number: 7)

Response:

Although the NRC does not believe that the definition of a laboratory confirmed positive test result should be modified from that proposed, it concurs with the commenters' concerns and has added guidance to section 2.9(c) of Appendix A to assure that an employee's unavailability does not prevent a final decision as to whether a laboratory-confirmed positive test result is evidence of an FFD policy violation. Section 2.9(c) has been revised to allow a laboratory-confirmed positive test to be declared a FFD policy violation in the following three circumstances:

- 1) if the individual expressly declines the opportunity to discuss the test results with the MRO;
- 2) if after a best effort to contact an individual for a 14-day period, the MRO has not been able to meet with the individual; or
- 3) if the licensee representative has successfully made and documented contact with the individual and instructed him or her to contact the MRO and more than five days have passed since the individual was contacted.

Accommodations are to be made for revisiting and potentially revising this determination if the employee later becomes available and it is determined that there was a legitimate reason for the delay in contacting the MRO. Additionally, if the individual is not available to the MRO for legitimate reasons known to the licensee (e.g., vacation, injury, assignment to duties off site), the licensee should postpone the determination until the employee has had a reasonable opportunity to contact the MRO. Also, should a suitable inquiry be received sometime in the future, the inquiring licensee should be informed of the laboratory confirmed positive and the fact that the MRO could not contact the individual to verify the results.

6.3.5 Unconfirmed Positive: Request for Change to Presumptive Positive

Comment:

One commenter suggested that the use of the term “unconfirmed positive test result” when referring to a specimen that screens positive on an immunoassay test, but negative on the confirmatory test, is misleading. Current use implies that the specimen definitely contained the drug or metabolite of interest but was not confirmed by GC/MS. Presumptive Positive gives the correct interpretation of the screening result. (Identification number: 25)

Response:

The NRC concurs and will delete the proposed term “unconfirmed positive test result” and replace it with the term “presumptive positive screening test result.”

6.3.6 Unconfirmed Positive: Proposal for Additional Detail

Comment:

One commenter recommended that the definition for “unconfirmed positive test result” be revised to indicate that screening tests must use an immunoassay, that such tests may indicate the presence of more than one drug or drug metabolite, and that such results indicate the presence of such drug(s) or metabolite(s) at or above screening cut-off levels. (Identification number: 36)

Response:

The NRC has declined to adopt these changes because all these matters are adequately specified elsewhere in the rule or Appendix A and need not be addressed in this definition. For example, the definition of "screening test" includes use of an immunoassay and section 2.7 of Appendix A establishes cut-off levels to determine whether a specimen is negative for the indicated substance. As noted in 6.3.5 and 6.3.7, the term "unconfirmed positive" has been changed to "presumptive positive screening test result."

6.3.7 Unconfirmed Positive Test: Changed to Presumptive Positive Screening Test Result

Comment:

A commenter suggested that the term “unconfirmed positive test” be deleted because it is a replacement for “presumptive positive” and since “screening test” is replacing “initial test,” a positive test can be referred to as a positive screening test. (Identification number: 10)

Response:

The NRC concurs and has deleted the proposed term “unconfirmed positive test result” and replaced it with the term “presumptive positive screening test result.”

6.3.8 Screening Test

Comment:

Two commenters suggested that the NRC delete the second sentence of the proposed definition for “screening test,” which requires that specimens identified as positives as a result of the on-site screening test be sent to the HHS-certified laboratory for confirmatory testing. One commenter objected to the implication that all specimens must receive both a second screen and confirmation testing by a HHS-certified laboratory. The commenter mentioned that experience has indicated that specimens identified as positive based on on-site screening and which are subsequently reported as negative from the HHS-certified laboratory were reported as negative as a result of the initial screening test, not the GC/MS confirmation test. The specimens with positive on-site screening test results should be allowed to be taken directly to GC/MS, which would address concerns regarding specimen degradation and deterioration. (Identification numbers: 10; 36)

Response:

Although the definition of “screening test” was not a proposed change and therefore not subject to public comment, the comment raises an issue that should be addressed.

The full definition of “screening test” is necessary to make the distinction between the first screening test done at the licensee's testing facility and the second screening test conducted at the HHS-certified laboratory. In addition to specimen degradation causing different screening results in some cases, the more frequent cause is the use of a different or more specific screening test by the laboratory.

HHS and its Drug Testing Advisory Board have been adamant that proper preparation of a specimen for GC/MS testing must include the screening test to determine dilution factor if there is a high concentration level; this is intended to insure there is a sufficient quantity of specimen remaining for any retesting. Furthermore, the rule allows licensees to have all “suspect” specimens tested with GC/MS regardless of the HHS certified laboratory's screening test results.

6.3.9 Limit of Detection

Comment:

One commenter suggested that the part of the proposed definition of “limit of detection” that references cut-off levels should be relocated to section 2.7(g). (Identification number: 25)

Response:

The NRC has considered this suggestion and decided that the current location of the statement that the limit of detection should be significantly lower than the established cut-off levels is appropriate in the definition of this term.

6.4 Definitions — Supervisor

One commenter suggested that the definition of “supervisor” be the same as the National Labor Relations Board’s definition and two other commenters suggested that the definition include the behavioral observation duties of the supervisor.

6.4.1 Supervisor: Request for NLRB Definition

Comment:

One commenter suggested that the proposed definition for Supervisor is unnecessarily broad. It could apply to almost any person at some time. The commenter suggested that the National Labor Relations Board definition be used instead. (Identification number: 36)

Response:

[Note, following definition cite is from 29 CFR 452.47 — with minor differences in grammar and punctuation, this is the same definition the commenter states is from 29 CFR 152.]

Under section 2(11) of the Labor Management Relations Act (29 CFR 452.47), supervisors include individuals “having authority, in the interest of the employer, to hire, transfer, suspend, lay off, recall, promote, discharge, assign, reward or discipline other employees, or responsibly to direct them, or to adjust their grievances, or effectively to recommend such action, if in connection with the foregoing the exercise of such authority, is not of a merely routine or clerical nature, but requires the use of independent judgment.”

This definition does not address the day to day oversight of an individual’s activities as is intended in the NRC definition. The definition proposed by the NRC provides licensees with the necessary flexibility to account for the various supervisory roles that occur within the plant’s operations (e.g., designated team leaders, “gang bosses,” supervisors of vendors, etc.). In general, factors that define supervisory positions include the person who is responsible for behavioral observation of workers, who is in responsible charge of the work, and who is responsible for evaluating the performance of the work.

6.4.2 Supervisor: Proposed Additions to Definition

Comment:

Commenters suggested that the proposed definition of “supervisor” be revised to clarify that supervisors are to implement behavioral observation techniques in the course of their routine contact with other personnel with unescorted access. The definition should specify that supervisor behavioral observation duties are to be administered to all personnel, not just to those for whom the supervisor has immediate oversight responsibilities. (Identification numbers: 10; 26)

Response:

The NRC has not adopted the definition of “supervisor” as proposed. Awareness training should assure that all workers, regardless of supervisory responsibilities, are aware of their role in assuring a drug-free environment. In that regard, the NRC would expect any employee, and

particularly a supervisor, who observed a person whose fitness was questionable would initiate appropriate action, regardless of the employment relationship.

6.5 Other Definitions

Commenters suggested using HHS and DOT terminology with regards to the chain-of-custody form and revising the “HHS-certified laboratory” definition, and asked for clarification on and provided suggestions for the term “history of substance abuse.”

6.5.1 Chain-of-Custody Form

Comment:

One commenter recommended that the term “chain-of-custody form” be changed to “custody and control form” in the Appendix A section that explains the use and retention requirements for that form. The commenter explained that both HHS and DOT refer to the form used to account for the integrity for each specimen from the point of specimen collection to the time it is received by the testing laboratory as the custody-and-control form. The form used within the testing laboratory to track the specimen is referred to as the chain-of-custody form. (Identification number: 25)

Response:

On August 19, 1994, the DOT and HHS jointly published a revised chain-of-custody form to be used in Federal employee testing as well as by DOT-mandated testing programs (52 FR 42996). This form is known as the Federal Drug Testing Custody and Control Form (OMB Number 9999-0023). Those NRC licensees that test urine specimens for only the five drugs specified in Appendix A to Part 26 and at cut-off levels prescribed in the HHS Mandatory Guidelines can use that form to maintain specimen chain of custody. That form is not suitable for use by licensees that test for additional drugs or use cut-off levels different from those established by HHS in its laboratory certification program. Those licensees should use a “look alike” form that accomplishes the same specimen security and accountability tracking purposes. To avoid confusion, the term “chain-of-custody form” in the rule has been changed to “custody and control form”. References to chain-of-custody procedures will continue to be referred to as “chain-of-custody”. References to the form used within the testing laboratory to track a specimen will continue to refer to the chain-of-custody form.

6.5.2 HHS-Certified Laboratory

Comment:

One commenter suggested the term “urine testing” be moved to revise the definition of “HHS-certified laboratory” as follows: “HHS-certified laboratory” means a laboratory that is certified to perform urine drug testing under the Department of Health and Human Services (HHS) “Mandatory Guidelines for Federal Workplace Drug Testing Programs.” (Identification number: 36)

Response:

The NRC has made the suggested edit to eliminate the implication that HHS-certified laboratories only do urine testing. The reworded definition makes clear that these laboratories are certified by HHS to do urine testing and may do other types of testing as well.

6.5.3 History of Substance Abuse

Comment:

Two commenters asked that the meaning of “history of substance abuse” as used in section 26.24(a) be clarified. One of these commenters suggested that it be defined as “the evaluated results of the prior 5-year suitable inquiries that indicate use of illegal drugs or the abuse of legal drugs including alcohol, prescription drugs, and over-the-counter substances.” One commenter also wanted the NRC to make it clear that the phrase does not necessitate a need for a new FFD history tracking requirement and that current suitable inquiry processes remain sufficient. (Identification numbers: 7; 6008)

Response:

A definition of "history of substance abuse" has been added to the rule.

The current suitable inquiry requirements should provide adequate tracking. No additional tracking for a history of substance abuse, beyond that required in the original rule (e.g., maintaining records of violations), is intended.

7.0 Testing Required Under 10 CFR Part 26

Several comments were received in reference to proposed revisions in the testing required under Part 26. Specifically, commenters responded to changes in requirements in preaccess, random, for-cause, follow-up, and return-to-duty testing. A number of comments also raised other general testing and procedural concerns.

7.1 Preaccess Testing

Several commenters raised issues regarding the proposed revisions to preaccess testing and specimen collection procedures. Many commenters argued that the revisions make the implementation of the process too complicated and burdensome for licensees. Others took issue with specific changes, such as the procedures through which unescorted access is granted to workers previously covered under another program. Several commenters offered alternatives to the proposed process. Some commenters recognized the NRC's attempt to reduce in-processing burden. Other commenters requested clarification regarding the administration of specific aspects of preaccess testing.

7.1.1 Preaccess Testing: Complications of Tracking New Information

Comment:

Three commenters were concerned about the complicated in-processing tracking and management procedures that would be necessary in order to comply with the proposed changes to section 26.24 regarding preaccess testing. Specifically mentioned was the risk of inadvertent non-compliance during peak outages when several transient workers go through the screening process. (Identification numbers: 7; 14; 15; 36; 6004)

Response:

Tracking of an individual as part of the preaccess processing has always been required under sections 26.27(a) and 73.56. The revision provides some additional flexibility to licensees. These changes will allow program efficiencies in that some unnecessary preaccess testing could be eliminated and some workers who have demonstrated reliability could gain immediate access rather than having to wait for negative test results. If a licensee is unable to take advantage of these efficiencies at this time because the industry's data base does not contain the necessary information, the licensee can continue to conduct preaccess testing according to the same procedures it has used for the past several years. These rule relaxations are being put in place now to provide the benefits where they can be realized and to accommodate any action by the industry should it wish to revise the data it collects regarding workers' employment periods so as to be able to achieve these program efficiencies on a broader scale.

7.1.2 Preaccess Testing: History of Substance Abuse

Comment:

One commenter stated that the requirement to conduct preaccess tests for all employees who have a history of substance abuse is an additional burden that was not contained in the original rule. In this commenter's view, the decision to test individuals with a substance abuse history, but who have successfully met the reinstatement to duty requirements and were covered by a program meeting rule requirements for at least 30 days during the 60 days immediately prior to transferring to another licensee, should be a licensee decision. (Identification number: 36)

Response:

The NRC is not adding a new requirement for preaccess testing of applicants who have a history of substance abuse. The rule has always required the preaccess testing of all applicants for unescorted access. The NRC has chosen not to relax testing requirements for applicants who have a history of substance abuse. The NRC's review of research on the probabilities of relapse suggests that heightened vigilance is required for individuals with a history of substance abuse and especially during job/employer changes. While preaccess testing requirements have been relaxed for certain categories of individuals, they cannot be relaxed for individuals with a history of substance abuse.

7.1.3 Preaccess Testing: Initial Granting of Access

Comment:

Two commenters agreed that relaxing the preaccess testing requirements will provide some reduction in burden. However, some commenters were concerned that the phrase "initial granting of access" in section 26.24 (a)(1)(i) implies a first and only condition. To avoid narrow limitations, the commenters suggest that the preaccess testing section distinguish between the two categories of individuals requiring preaccess testing: those who require preaccess testing for the first time and those who require "reinstatement testing." The commenters proposed that the re-instatement requirements would also be applicable to return-to-duty testing requirements. (Identification numbers: 7; 14; 15; 36)

Response:

While there are always alternative solutions to addressing rule revisions, the NRC believes that this change is not necessary and is concerned that it would create an unnecessary and confusing new definition and worker category.

7.1.4 Preaccess Testing: Access Prior to Negative Test Result

Comment:

Several commenters stated that the proposed revisions allowing unescorted access prior to the receipt of a negative test result to workers who have recently been covered by a program that meets the requirement of the rule or have had a recent negative drug test to be too restrictive. Some commenters recommended that this change also include workers with less recent coverage by a program or a less recent test result. Some commenters also suggested that workers be

granted unescorted access upon specimen collection, but before receipt of a negative test result, if they had been covered by a program meeting the necessary standards in the 60 days immediately prior to the test. Similarly, it was suggested that workers who were favorably discharged from a FFD program during the previous 60-365 days should also be granted unescorted access prior to receipt of negative test results. (Identification numbers: 7; 10; 15; 36)

Response:

The revision to section 26.24(a) as adopted reflects the maximum amount of flexibility and departures from previous requirements for testing all applicants and awaiting test results that are considered prudent and reasonable by the NRC.

7.1.5 Preaccess Testing: Awaiting Negative Test Result

Comment:

One commenter recommended that licensees be authorized to grant initial unescorted access, after collection of specimens, and with negative breath alcohol test results, while drug test results are pending to all applicants. (Identification numbers: 20)

Response:

The NRC has provided this option for workers with a specifically defined history. Based on the higher positive test results for preaccess tests, allowing this relief to all applicants, regardless of previous history, would create too high a risk.

7.1.6 Preaccess Testing: Preaccess Testing as Scheduled and Announced

Comment:

One commenter requested clarification as to whether or not preaccess testing can be a scheduled, announced test. If so, licensees would have the flexibility of having their contractors and vendors tested at their home sites, before arrival at the reactor, which would expedite service work at the reactors. The commenter acknowledged that specimens for such preaccess testing would have to be tested by a HHS-certified laboratory. (Identification number: 33)

Response:

Preaccess testing is expected to be a scheduled, announced test. Contractors and vendors can be tested under another program that meets the standards of Part 26 and has been reviewed and accepted by a licensee. In addition, sample collection and testing by any HHS-certified laboratory that is under contract to any licensee under 10 CFR Part 26 would be acceptable.

7.1.7 Preaccess Testing: Consistency with Access Authorization Rule

Comment:

A commenter noted the potential for a conflict between the Access Authorization Program requirements for a negative test result during the past sixty days and the revision which indicates that a pre-access test is not required if the individual has been covered by a behavioral observation program for thirty of the past sixty days. (Identification number: 5002)

Response:

The access authorization rule does not address drug testing. Some of the documents provided by NEI to industry have combined access authorization and FFD implementation guidance and may need to be revised. The NRC sees no conflict between the requirement to obtain a negative test result during the 60 days prior to granting unescorted access and the exception to that requirement when the specified conditions, which include being covered by an FFD program for at least 30 of the previous 60 days, are met.

7.1.8 Preaccess Testing: Alternatives to NRC Proposed Burden Reduction

Comment:

In the interests of decreasing burden, saving time, and saving money on on-site testing costs, one commenter suggested that licensees be authorized to grant unescorted access to “craft” personnel while the results from the drug test are still pending when they are returning to a utility after an absence of no more than a year and if they have a negative alcohol test, have no previous history of drug abuse, and were terminated favorably.

Another commenter recommended that, after a preaccess test specimen is collected from the individual, unescorted access should be granted to previously covered workers who were favorably discharged from a program meeting the requirements of the rule during the previous 60 to 365 day period. (Identification number: 7; 6009)

Response:

The revision to section 26.24(a) as adopted reflects the maximum amount of flexibility and exceptions considered prudent and reasonable by the NRC.

7.2 Random Testing

Commenters requested clarification regarding the practical implementation of a “random” testing selection process. Questions were raised about shift issues, excused absences, and testing of corporate employees. Several commenters disagreed with the procedure to test selected, but unavailable, workers as soon as they return to the site. The practice of random testing in general was challenged as an invasion of privacy.

7.2.1 Random Testing: Individuals Not Available for Testing when Selected

Comment:

Several commenters responded to the proposed revisions to clarify the requirements for random testing of individuals who are not available for testing when they are selected. Most of the commenters defended their current practice of returning to the selection pool the names of individuals who were not available for testing when selected as being more feasible and creating less of an administrative burden than flagging badges and testing individuals the next time random testing is conducted and the persons are on site. Behavioral observation and return to work requirements for those with 60 or more days of absences were cited as “fail-safe” measures that ensure fitness-for-duty. Other commenters suggested that badges should be flagged only if the individuals have not been tested for an extended period of time, such as 60 days, due to unavailability. Other commenters agreed with the NRC’s proposed clarification. Some noted that

their practices already conformed to the proposed clarification and have experienced no administrative burden. Commenters also raised other concerns pertaining to this rule modification: (1) the rule puts an unfair burden on companies that do not have a system in place that integrates FFD and access control systems and (2) the proposed rule change should address the differences between contractors, with whom supervisors have less general familiarity because of their irregular presence on site, and licensees. (Identification numbers: 1; 7; 10; 12; 14; 15; 21; 23; 28; 32; 36; 6005; 6006; 6010; 6011)

Response:

The NRC has clarified the random testing requirements in response to cases of random testing practices that involve simply returning the names of the individuals who are selected for testing but not on site to the "pool" and testing those who are available. This practice subjects those individuals who are routinely on site to random testing at a higher frequency than those who are not routinely on site. This issue was addressed clearly in responses to comments on the original proposed rule (see NUREG 1354) and in NUREG 1385 which responds to implementation questions. The practice of returning individual's names to the testing pool without testing is not consistent with the requirement that all persons in the testing pool have an equal probability of being selected and tested. The NRC declines to distinguish between licensee employees and contractors with regard to this aspect of random testing.

7.2.2 Random Testing: Guidance on Implementation

Comment:

Several commenters requested guidance as to how "random" testing is implemented "in practice." Commenters questioned if the rule modification would alter randomness, or if their current procedures align with randomness. For example, requiring the licensee to test the person when he or she returns to the site reduces the element of randomness. Other commenters focused on the definition of random selection by either indicating that they select on the basis of shift and other factors, or by questioning if these are appropriate factors to consider in random selection. Commenters also questioned whether shifts should be randomly selected in proportion to their occurrence (e.g., 30% of shifts are weekend, 60% are backshifts, and so on). (Identification numbers: 1; 20; 5002; 6006)

Response:

Appropriate techniques for random testing and related issues were addressed in NUREGs 1385 and 1354. The key to random testing is the equal chance of any employee being selected and tested and its unpredictability (i.e., no prior awareness of the test). The NRC recognizes that some "predictability" would creep in if those employees absent for extended periods could reasonably predict that they had been selected for testing during their absence. However, most workers will not be absent that long and the deterrent effect will continue to exist. The rule does not specify how the personnel from various shifts and weekends should be selected for testing nor does the NRC desire to prescribe such procedures. Any approach that provides reasonable assurance of an equal probability of being tested and that there are no "safe havens" would be acceptable.

7.2.3 Random Testing: Reasonableness

Comment:

One commenter objected to the practice of random testing, in general. The commenter believed random testing to be an unreasonable invasion of worker privacy, that has little deterrent effect and is not directly connected with work performance. The commenter suggested that behavioral observation, for cause, worker peer pressure, and education regarding the toxic and deleterious effects of substance abuse are more effective deterrents for substance abuse in the work place. (Identification number: 17)

Response:

This comment does not relate to a proposed change to the rule, however, it raises again a significant policy issue. The NRC continues to believe that random testing is an important aspect of a complete FFD program. The commenter may also want to review section 7.1 of NUREG 1354 and Chapter 5 of NUREG/CR-6470 for a more thorough discussion of this topic. The NRC intends to address the scope of random testing in a separate rulemaking.

7.2.4 Random Testing: Excused Absences

Comment:

One commenter asked for clarification as to how excused absences are defined and treated in the random selection process. For example, is testing required of an individual who is not on duty, is on site for personal reasons, and has been selected for random testing? (Identification number: 5002)

Response:

An employee who is selected for testing should be tested at the earliest reasonable and practical opportunity. If someone with unescorted access is in the protected area of a nuclear power plant, the person must report for testing whether he or she is there for personal or professional reasons.

7.2.5 Random Testing: Testing Upon Return to Site

Comment:

Several commenters thought that requiring employees to be tested as soon as they return to the site (if selected in the random process and unavailable) poses a cumbersome and unnecessary burden on the licensee. It also assumes that FFD staff have a constant presence on site. The commenters recommended that contractors should be required to adhere to this requirement, but not licensees, because licensees track absences for their staff but not for contractor staff. (Identification numbers: 7; 36; 6005; 6010)

Response:

The NRC has provided additional language to clarify the intended flexibility of the requirement. The NRC expects individuals selected for testing to be tested at the earliest reasonable and practical opportunity after returning to the site, and to be tested without notification of the testing until immediately prior to testing. It is not the NRC's intent to require collection facilities to be

attended 24 hours a day, or that collection personnel be called in to administer the random tests; the language of the rule has been edited to clarify this area. Both licensee and contractor employees are covered equally by this provision.

7.2.6 Random Testing: Corporate Employees

Comment:

Commenters requested guidance about how to handle the random testing of corporate employees and asked whether a separate random test pool should be used. (Identification numbers: 6010; 6022)

Response:

It is permissible in cases when there are no collection personnel at the corporate offices for corporate workers to be tested when they come on site or to send medical staff from the site to corporate headquarters on occasion to collect specimens. Note that this should be a rare occurrence because the rule permits the use of non-medical personnel provided they are trained and demonstrate proficiency (see section 2.2(d)(2) of Appendix A). The NRC hopes that this question does not imply that the commenters are aware of cases in which such employees are not being tested when selected for random testing. Licensees may create a separate pool for corporate employees but cannot discriminate within any random testing pool.

7.3 For-Cause Testing

Several comments were received regarding for-cause testing. These comments were generally either objections to proposed revisions or requests for clarification. Some commenters disagreed with the proposed changes that specify when for-cause testing must occur, such as following attempts to subvert the testing process or upon receiving credible allegations of substance abuse. Others commenters raised concerns and questions regarding the requirement for medical determination of fitness before unescorted access can be reinstated following a for-cause test.

Several commenters were also concerned about some of the procedural issues of for-cause testing, such as the proposed time limits for obtaining for-cause samples. Several requests for clarification were also received regarding appropriate procedures for special situations, including medical emergencies.

7.3.1 For-Cause Testing

Comment:

Commenters disagreed with the requirement of a for-cause test upon receiving credible information that a person is abusing drugs or alcohol on the basis that the information may be received several days after the offense actually occurred. (Identification numbers: 17; 5002)

Response:

For-cause testing has always been required by the rule as an appropriate response to a credible allegation of substance abuse, even if the allegation refers to an earlier activity.

7.3.2 For-Cause Testing: Attempts to Subvert

Comment:

Several commenters disagreed with the proposed rule change that included the specification of "attempts to subvert" as one of the requirements (in addition to "following any observed behavior or physical condition that creates a reasonable suspicion of possible substance abuse") for for-cause testing procedures. Some commenters felt that the original wording of the rule was adequate and included subversion attempts when appropriate. Another commenter pointed out that the requirement of a for-cause test might compromise the ability to deny unescorted access on the basis of subversion if the test result is negative or shows no signs of adulteration or dilution, even though subversion did occur. Furthermore, the commenter stated that the proposed requirement would be redundant in view of section 2.4(g)(15)(ii), which authorizes an observed collection if there is reason to believe that an attempt to subvert the testing process has occurred. (Identification numbers: 7; 20; 36)

Response:

The NRC agrees that the language would have been redundant and could have lead to misinterpretation of the intent of the provision. When subversion is indicated, an MRO and/or a licensee may determine that a for-cause test is an appropriate action in some cases, but is not advised in other cases. The text has been edited accordingly.

7.3.3 For-Cause Testing: Time Limits

Comment:

Two commenters raised concerns about the proposed time limits for obtaining for-cause samples. Although commenters appreciated the proposed guidance, they said the time constraints could create problems in that, due to operational considerations, testing may not be possible within the specified time and thus results could be deemed invalid, in spite of a positive test result. Also one of the commenters warned that licensees may sacrifice due process and sufficient review in order to comply with the proposed time specifications. (Identification numbers: 12; 21)

Response:

The NRC has considered the comments and edited the section to assure that the language reflects the original intent that the rule maintains appropriate flexibility in addition to providing guidance.

7.3.4 For-Cause Testing: Determining Fitness to Return to Duty

Comment:

Several commenters addressed the proposed change to the rule which would clarify that an MRO or other licensed medical person must determine the fitness for duty of an individual tested for cause before the worker can be returned to duty. Two commenters suggested that section 26.24(a)(3)(ii) be changed so that it is clear that a medical determination of fitness before returning to duty is not required if an individual is tested on the basis of suspicion of alcohol use and the breath analysis results are negative. However, other commenters suggested that the safe and conservative approach would be to suspend the employee's unescorted access until a negative

result from the drug test has been received as well. Another commenter requested clarification as to whether or not a medical determination of fitness is required before unescorted access can be re-instated if test results are negative. One commenter mentioned that many licensees do not have an MRO available on site 24 hours a day, which would delay the individual's return to duty. (Identification numbers: 7; 20; 23; 28; 29; 36; 5002; 6019)

Response:

The Commission has decided not to adopt the requirement that a medical determination of fitness be performed to evaluate employees who test negative in a for-cause test. In situations such as preaccess and return-to-duty testing, the fitness determination is ordinarily made during normal work hours when the MRO is on-duty. By contrast, the need for a medical determination after a negative for-cause test could occur during off-normal work hours when the MRO is not available. In this situation, the licensee would have the following options: (1) provide an MRO on a 24-hour or as-needed basis or (2) defer the medical determination until normal work hours. The added costs and reduced flexibility would only occur in negative for-cause tests and there is insufficient data to show that such costs would be justified in terms of the identification of significant numbers of unfit workers would only be identified as unfit by the MRO. Therefore, the Commission has decided that a medical determination after a negative for-cause test is not warranted.

7.3.5 For-Cause Testing: Testing Under Adverse Conditions

Comment:

One commenter sought guidance as to the acceptability of using alternative testing methods in extreme cases, such as medical emergencies in which the hospital administering medical treatment uses its own testing procedures. (Identification number: 5002)

Response:

In cases of medical emergencies, the first priority is always the health and safety of the people involved. When possible and appropriate, testing under Part 26 should be accomplished. The new section 26.24(i) provides guidance for situations in which collection of breath, blood, or urine specimens is difficult or hazardous.

7.3.6 For-Cause Testing: Testing at LOD

Comment:

One commenter sought guidance as to the circumstances for which it would be acceptable to test at the limit of detection in for-cause testing situations. (Identification number: 5002)

Response:

The rule has always provided the flexibility to test at the limit of detection for all for-cause testing.

7.3.7 For-Cause Testing: Alcohol Only Test

Comment:

One commenter pointed out that the NRC indicated that it declined a previous recommendation to adopt an "alcohol only" test. The commenter found this to be inconsistent with section 26.20 (e)(2) which provides for an alcohol only determination of fitness in call-in situations. (Identification number: 36)

Response:

The revision to section 26.20(e)(1) is intended to assure all FFD concerns are addressed in a call-in situation. The requirement for an alcohol evaluation under section 26.20(e)(2) is not an "alcohol only" for-cause test. This is a test in response to a self-reported use of alcohol which should not be any violation under 10 CFR Part 26, but which may indicate that the individual is impaired and that special accommodations may be needed.

7.3.8 For-Cause Testing: Supervisor Referrals

Comment:

Two commenters focused on supervisors' willingness to identify workers for for-cause testing. Commenters expressed concern that supervisors may be less inclined to refer individuals in for-cause situations if the referral results in automatic suspension of unescorted access with reinstatement dependent on a medical determination of fitness that may take several days. Suspended access for lengthy periods of time may be inappropriate and undesirable because of staff shortages from downsizing. Instead, supervisors may prefer to deal with suspected use in another manner rather than penalize workers by suspending access. (Identification numbers: 36; 6014)

Response:

Except for isolated incidents, the NRC has not seen evidence that indicates an unwillingness on the part of supervisors to refer workers for for-cause testing. The NRC expects supervisors to continue to be well trained and to recognize the risks of allowing individuals of questionable fitness for duty to continue working in the protected area. Furthermore, the NRC expects that all individuals suspected of being impaired are removed until determined to be fit and that licensee policy (written and unwritten) does not discourage supervisors from making referrals. See also NUREG 1385 items 8.1.3; 8.2.2; 8.2.10; 8.2.14 and NUREG/CR 5227 Supplement 1 p.4-4 and the Discussion in 54 FR 36801 of September 22, 1988.

7.4 Follow-Up Testing

The proposed revisions to the follow-up testing requirements, which were primarily moving the requirements from section 26.27(b)(4) to section 26.24(a)(4) with minor revisions proposed to clarify the testing procedures, elicited a number of comments. Several commenters took exception to the duration of the follow-up testing requirement which had always been required by the rule. Several other comments were received requesting additional clarification regarding the circumstances under which follow-up testing is required.

7.4.1 Follow-Up Testing: Duration

Comment:

Two commenters disagreed with the duration of the follow-up testing requirement. One commenter proposes a two-year follow-up program. Another recommended that, instead of the existing three-year follow-up testing requirement with its specific monthly interval testing requirements, follow-up testing should be required for only one year after return to duty — the number and frequency of such follow-up testing to be determined by the MRO and consist of at least six tests in the first 12 months. The MRO, if satisfied with the individual's rehabilitation, may terminate the requirement for further follow-up testing. The commenter's rationale for this suggestion was that specifying a 36-month follow-up testing period would essentially eliminate the MRO from the process, inhibiting the ability to tailor the program to the individual's medical history. The commenter noted that data show that most recidivism occurs during the first year, and behavioral observation and routine testing programs are sufficient coverage after this period. (Identification numbers: 5; 7)

Response:

Although the follow-up testing requirements have always been required and have not been changed, they have been clarified regarding how they apply after the first positive test result. The NRC has determined, based on literature review and consulting with recognized experts, that the 36-month period is the minimum required to assure continued abstinence. The NRC anticipates that MROs or the licensed physician will make determinations of appropriate follow-up testing requirements, which may be more frequent or of a greater duration than the minimum specified in the rule.

7.4.2 Follow-Up Testing: Follow-Up Period

Comment:

One commenter pointed out that the original rule did not require a 36-month follow-up testing regimen after the first confirmed positive drug test, though it did require such follow-up testing after a second positive drug test or following sale, use, or possession of legal drugs while within the protected area. Given this, the commenter suggested that the NRC adopt language similar to DOT follow-up testing requirements. DOT requires MRO direction of follow-up testing requirements and requires a minimum of six tests in the first 12 months following return to duty. (Identification number: 15)

Response:

The follow-up testing requirements were misplaced in the original rule. The NRC does not consider moving existing requirements to be equivalent to creating a new requirement.

Given the safety-sensitive nature of the nuclear industry, the NRC believes that it should take a conservative approach to follow-up testing.

7.4.3 Follow-Up Testing: Prescription and OTC Drugs

Comment:

One commenter suggested that follow-up testing requirements need further elaboration. The commenter stated that it is not clear what is expected if a person abuses prescription or over-the-counter (OTC) drugs. (Identification number: 7)

Response:

Legal drug abuse is covered under the rule but requirements for determining violations, sanctions, and follow-up testing are up to the licensee, except in the case of alcohol. Use of an illegally obtained prescription drug should be treated as illegal drug use and sanctioned as a violation of FFD policy. Follow-up testing should include the drugs from which the employee should be abstaining (i.e., the specific substance or compound in the prescription or OTC medication that the employee has been abusing). MROs may use their judgment regarding whether use of a prescription drug that was prescribed for someone else (e.g., a spouse) or an OTC drug is abuse of a legal drug. Section 2.1(b) of Appendix A of the rule has been modified to clarify that any drug suspected of having been abused can be included in return-to-duty testing of employees who have previously been removed from access and any test of an employee who is in a follow-up testing program.

7.4.4 Follow-Up Testing: Second Positive Test Results

Comment:

One commenter was concerned about the proposed revision to sections 26.27(b)(2) and (3) because of the possibility a second positive test result can be caused by the drug use indicated by the first positive result. Due to numerous physiological reasons, it is unlikely that it can be unequivocally determined, that the second positive result is not related to use in the first positive test result. Issues of due process also come into play. Consequentially, the commenter recommended deletion of the proposed rule revision to section 26.27(b)(3) which would require action on a positive test resulting during an assessment or treatment period. (Identification number: 36)

Response:

The NRC recognizes that under some circumstances a second positive test result during the follow-up and treatment period is possible even when the person has not used the drug in question after producing the specimen that led to the first positive result. Such instances, however, are rare and a decreased level of the drug or drug metabolite would be expected.

In some cases, the MRO may determine that the "second positive" is due to continued presence of the drug from the originally detected use rather than additional use. In that case, the MRO has determined that "second positive" has a legitimate medical explanation and makes the result negative, therefore no subsequent violation of policy occurred. The NRC sees no need to further revise section 26.24(b)(3) as recommended by the commenter. Also see Summary Comment 15.3.2.

7.4.5 Follow-Up Testing: Behavior Not Involving Substance Abuse

Comment:

One commenter questioned why follow-up tests are required for behavioral issues that result in a violation of the FFD rule, but which do not involve drug or alcohol use. (Identification number: 5002)

Response:

Follow-up testing is not required for violations that do not involve drug or alcohol use. Follow-up testing is required for those being returned to duty under section 26.27(b)(3) and (5) subsequent to removal for drug or alcohol abuse or sale.

7.4.6 Follow-Up Testing: EAP Referral

Comment:

One commenter raised the issue of whether people who refer themselves to an EAP, but are not subject to the sanctions related to having tested positive on a drug or alcohol test, are required to receive follow-up testing. (Identification number: 6006)

Response:

EAPs should require appropriate follow-up testing and monitoring of the patient's progress in coping with the diagnosed problem as part of the treatment program. Specific requirements for follow-up testing for self referrals are not prescribed in the rule.

7.4.7 Follow-Up Testing: Licensee's Responsibilities

Comment:

One commenter asked for clarification as to whether licensees are responsible for ensuring that the specific frequency of follow-up testing (which may be a subjective decision) is actually carried out. (Identification number: 6006)

Response:

Licensees are responsible for ensuring that follow-up testing is carried out as specified in the rule, or consistent with a more conservative testing program to meet the patient's specific needs.

7.4.8 Follow-Up Testing: Hazards to Public Health and Safety

Comment:

One commenter asked for clarification regarding whether those who are deemed to be a potential hazard are subject to three year follow-up testing. (Identification number: 6006)

Response:

The NRC does not specify any sanctions for instances in which a person is removed as a hazard to public health and safety, but not for drug or alcohol or other action or condition specified as a violation of licensee FFD policy. These hazard-causing conditions could include fatigue, stress, depression, etc. Licensees must determine fitness and make a decision regarding appropriate return to work and follow-up requirements in these cases. Licensees and their EAPs are allowed considerable flexibility in the way they handle these situations and are expected to use prudent judgment to assure public health and safety.

7.4.9 Follow-Up Testing: Testing at LOD

Comment:

Two commenters recommended an addition to the rule that would require that follow-up testing be only for detection of drug or alcohol use, not positive or negative at the cut-off levels, on the basis that people may not be abstaining from use even if the test results do not show positive results. (Identification number: 15, 6009)

Response:

This practice is clearly allowed under Part 26. However, the NRC declines to require LOD testing for all follow-up testing specimens. The rule has always permitted using more conservative (i.e., lower) cut-off levels, a practice which would be especially appropriate for for-cause and follow-up testing. Also, the rule permits testing for other drugs, and if the licensee is aware that a worker is using a drug not covered by its normal drug panel, the drug of interest should be involved in for-cause, return-to-duty, and follow-up testing.

7.5 Return-to-Duty Testing

Several commenters expressed concerns about the proposed chemical testing requirements in section 26.24(a)(2) in relation to return-to-duty testing. Many comments pertained to the requirements for return-to-duty testing and pre-access testing in relation to specific aspects of the individual's previous history in a FFD program. Because these issues also concern preaccess testing, they are summarized and addressed in section 7.1.4, Preaccess Testing. Some commenters proposed that the rule make an explicit distinction between the different circumstances under which return-to-duty testing occurs. Other commenters expressed concerns regarding the assessment process prior to returning to duty. Some commenters indicated areas of confusion with the wording and interpretation of the proposed revisions for this section, in particular regarding return-to-duty testing after absences.

7.5.1 Return-to-Duty Testing: Creating Additional Categories of Workers

Comment:

Commenters proposed a simplification of the process by which unescorted access is granted to workers returning to duty. It was suggested that to clarify the rule, two categories be created — one for initial preaccess testing, and one for reinstatement testing. (Identification numbers: 7; 36)

Response:

While the NRC recognizes that there are alternative methods for describing and defining the circumstances described under return-to-duty testing, the categories as proposed meet the NRC's regulatory requirements. Return-to-duty testing is, as noted by the commenters, primarily reinstatement testing but does not include preaccess testing. The changes creating return-to-duty testing requirements make clearer certain testing requirements in the original rule.

7.5.2 Return-to-Duty Testing: Assessment of Fitness for Return to Duty

Comment:

Two commenters believe that the requirement in section 26.27(b)(1), which stipulates that a licensed physician must make a medical determination of fitness before return to duty is authorized, is unnecessary and recommend that the licensee should be permitted to make this determination. (Identification numbers: 20; 29; 36).

Response:

Returning individuals who have been removed under section 26.27(b)(1) due to impairment, questionable fitness, or a violation of FFD policy should be thoroughly evaluated prior to their return to duty with unescorted access. The NRC continues to believe that a licensed physician has the appropriate training and experience to assess medical determination of fitness and anything less could present an unacceptable risk to safety.

7.5.3 Return-to-Duty Testing: Testing Requirements after Absences of 60 Days

Comment:

One commenter indicated that the intent of the proposed changes to return-to-duty testing requirements are inconsistent. Proposed changes suggest that individuals transferring from another location within 30 days need not be tested, while individuals returning to work at the same facility are waived from the testing requirement if they are returning within 60 days. The commenter believed the distinction between the two is unnecessary. Another commenter believed that the proposed changes incorrectly imply that badge non-usage is the same as absence, when in fact a worker may have just not needed to use unescorted access to protected areas. (Identification numbers: 23; 5002)

Response:

The NRC believes that it is appropriate to distinguish between employees transferring from other facilities and employees who are with the same employer but have been absent from the possibility of being tested. There is no implication that badge non-usage is the same as absence. Individuals may be available for testing when selected whether or not they are in the protected area.

7.5.4 Return-to-Duty Testing: Explicit Requirement for a Negative Test Result

Comment:

One commenter stated that section 26.27(b)(3) and (5) should explicitly state that a “negative” test result is necessary for return to duty. (Identification numbers: 20; 29; 36)

Response:

The NRC concurs that a negative test result is necessary prior to returning an individual to duty and has revised the rule accordingly.

7.5.5 Return-to-Duty Testing: Categorization of the Return-to-Work Test

Comment:

One commenter wondered why a return-to-work drug and alcohol test, after an individual is away from the site for more than 60 days is considered a random test instead of a preaccess test. (Identification number: 5002)

Response:

This provision applies only if the individual has been selected for random testing during his or her absence. This choice of categorization is for reporting purposes and is arbitrary. The NRC's intent is to be clear that only one test is required and to give guidance on how to count the test for reporting purposes.

7.5.6 Return-to-Duty Testing: Random Testing for Workers Infrequently on Site

Comment:

One commenter stated that the rule addition to return-to-duty testing in section 26.24(a)(5) may cause inconsistency in implementation because of the various ways of interpreting the phrase “possibility of testing” for returning workers. Licensees must determine if the worker was absent at the time of selection or not “reasonably” available for testing in a timely manner. It was recommended that the section be revised as: “Return-to-duty testing must be conducted when a person seeks reassignment to activities under the scope of this rule after having been denied such assignment under the provisions of section 26.27(b). A negative test result must be obtained before reassignment.” (Identification numbers: 36)

Response:

Return-to-duty testing covers two circumstances. One, someone has been denied access under section 26.27(b). Two, someone was not at risk of being tested (regardless of reason). The deterrence effect of random testing is lost if the individual is free from the possibility of being tested whether for legitimate or illegitimate reasons. Therefore, the NRC believes the two circumstances covered by the rule are appropriate and declines to adopt the comment. The NRC will accept reasonable inconsistencies arising from good faith efforts to determine whether a person can be tested during an "absence."

7.6 Procedures

Several comments were received regarding various elements of the testing process. Commenters expressed concerns about the proposed policy to include FFD personnel in the testing process and revised MRO requirements. A number of commenters responded to revisions in the chain-of-custody requirements, particularly regarding who is required to sign the forms. Other commenters expressed concerns with the revised procedures and policies affecting specimen temperature, shipments requirements, specimen collection, and notification time. Additional comments were also received requesting other procedural guidance and clarification.

7.6.1 Procedures: Inability to Provide a Specimen

Comment:

Two commenters requested suggestions regarding how to respond when an individual still could not provide a urine specimen after drinking 24 oz. of water. (Identification numbers: 1; 5002)

Response:

The rule requires the collection site person to contact the appropriate authority to obtain guidance. Under the circumstances described, it would be useful to determine whether the difficulty was a temporary inability or deliberate refusal. In some cases it may be appropriate to allow some more time. As a last resort, a medical determination may be an appropriate approach.

7.6.2 Procedures: Including FFD Personnel in Testing

Comment:

Many comments were received regarding the proposed changes which stipulate the inclusion of FFD personnel in testing procedures. These comments are summarized and addressed in section 5.2 (Identification numbers: 7; 20; 30; 6006)

Response:

See Comment Summaries under 5.2.

7.6.3 Procedures: Courier Companies

Comment:

There were objections to the requirement that there be a tracking system that identifies the courier company conveying the specimens to the laboratory because this is a burden, prescriptive, and reduces the flexibility that licensees have in accomplishing chain-of-custody requirements.

Two commenters disagreed with the proposed rule change in section 2.4(d), Appendix A and recommend that the Chain-of-Custody form should be signed by ALL handlers of the samples as is presently required. (Identification numbers: 7; 17; 20; 28)

Response:

As noted in the Discussion of the May 9, 1996 Federal Register notice, standard practice — acceptable for forensic purposes — is to have the courier company sign for and track the package of specimens rather than to sign the form for each individual specimen. This practice is well established and follows the same guidelines established by HHS, DOT, and DOJ.

The change to the rule makes it clear that couriers do not have to sign the custody-and-control forms. This change reflects lessons learned by HHS, DOT, and DOJ about custody requirements in response to a court case. Courier companies used by licensees routinely provide a tracking system such as that described.

7.6.4 Procedures: MRO Reviews

Comment:

Several commenters noted changes to the requirements for MRO reviews. Commenters approved of the elimination of the requirement that the MRO be notified and notify management of failure to cooperate, noting that this is an administrative, not a medical issue. Other commenters responded to changes that would require the MROs to review both positive and negative test results. (Identification numbers: 7; 20; 21; 24; 25; 32; 36; 6005)

Response:

The NRC concurs that failure to cooperate is a management, not a medical, issue. There is not a new requirement for MRO's to review negative test results. The MRO has always had access to all testing results. HHS Guidelines specify that all results be reviewed at a general level by the MRO. Prior to sending the results to the licensee it is expected that the negative test results will be reviewed as a group by the MRO, who may note any anomalies, false negatives (based on blind performance tests), low specific gravity or creatinine results which indicate a need for reanalysis, etc. Positive test results, in contrast, require a careful, individual review. Previously the rule, and the NRC's response to questions regarding MRO review of negative test results (such as the response under 5.8 of NUREG 1385) have inappropriately implied that the MRO makes no review of negative test results. In fact, HHS Guidelines and the NRC's FFD rule require that all tests be sent to the MRO for review. The in depth, specific and individual review of findings required for all positive results is not, however, expected for all negative results. See also Summary Comment 15.1.5.

7.6.5 Procedures: Shipment Time and Temperature Restrictions on Specimens

Comment:

One commenter recommended that the revisions regarding assurances that specimens are either chilled or transported to the laboratory be deleted and replaced with an advisory regarding specimen deterioration. The commenter argues that the detailed requirements would be difficult to monitor since many of the actors in the process do not come under licensee control. Another commenter recommended that the wording be simplified (and the requirements made more flexible) in order to make this section less confusing. Another commenter noted that the requirements that specimens be received at laboratories within 48 hours and screened within 72 hours would not be achievable over holiday weekends. The commenter recommended deleting this requirement. (Identification numbers: 7; 25; 36)

Response:

In order to continue to achieve the goal of preventing the deterioration of specimens while, as suggested, providing more flexibility, the NRC has edited the revision to this section to require licensees to send specimens as soon as reasonably possible or to take reasonable and prudent measures to assure that specimen deterioration does not occur. The requirement for receipt of the specimen at the laboratory within 48 hours of shipment and testing within 72 hours remains with flexibility provided for unusual circumstances.

7.6.6 Procedures: Split Specimen Procedures

Comment:

A commenter noted that since split specimens are not required by Part 26, the revisions should be careful not to imply that the lack of a split specimen, or a negative result from a split specimen, could invalidate a positive result from the primary specimen. There was also concern that the one-day response to a request for testing of the split specimen would be impractical due to weekends, holidays, etc. and that this requirement should be relaxed. Another commenter suggested a 2-3 day window for shipping of split specimens (rather than same day shipment). One commenter suggested that the licensee should not wait for the employee to ask for the split specimen to be tested, but rather that the licensee should automatically send the split specimen. It was suggested that the wording “second testing process” be changed to “testing of the split specimen” in section 2.7(k). (Identification numbers: 7; 21; 28; 36)

Response:

Split specimens are not required under Part 26. Guidance is provided for licensees choosing to include split specimens in their testing program and new language has been added to clarify that MROs should consider all information when making a determination. Automatically testing split specimens is not appropriate. Split specimens are tested only at the request of the donor. The current requirement that specimens be forwarded “that day” has been revised to “within three weekdays (Monday to Friday, not to include holidays)”. The NRC agrees that the wording “testing of the split specimen” is clearer than “second testing process” and has revised the section accordingly.

7.6.7 Procedures: Chain-of-Custody Documentation

Comment:

One commenter supported the change that the collection person shall note any unusual behavior on the chain-of-custody form. Another agreed with the use of the OMB form. Another suggested wording that the chain-of-custody forms be enclosed in rather than attached to the specimen shipping container. (Identification numbers: 20; 25; 36)

Response:

The NRC concurs that noting unusual behavior on the chain-of-custody form and the option to use the OMB approved form are desirable. The NRC concurs that it is useful to achieve as much consistency as possible across programs and that use of the OMB Custody and Control form is desirable. This form, however, is not suitable for use by licensees that test for additional drugs or use cut-off levels different from those established by HHS in its laboratory certification program.

Those licensees should use a "lookalike" that accomplishes the same purposes. The NRC will refer to this form as the custody-and-control form in the rule. Custody and Control (Chain-of-custody) forms should be attached to each urine specimen bottle which should be enclosed within a shipping container.

7.6.8 Procedures: Listing Prescriptions

Comment:

Five commenters responded to the proposed change in requirements regarding employee listing of prescription medications on the chain-of-custody form. One supported the change as written. Three commenters did not support the change. Two commenters suggested that this information is helpful in decision making related to questionable specimens. Another commenter stated that allowing this listing to wait until the employee meets with an MRO is not appropriate because the employee may not remember all the medications she/he used in the past 30 days. The fifth commenter asked if employees will have a choice whether or not to provide this information. (Identification numbers: 14; 20; 28; 32; 5002)

Response:

This change is consistent with the Americans with Disabilities Act. The employer has no need to know what medications an employee has taken unless they are relevant to a test result. If there is a positive result, the individual will have to provide proof of any prescription to the MRO regardless of what medications were listed on the form. Although test results are typically returned within a week, individuals who are concerned that they will not remember all medications should be encouraged to keep a private listing in case it is needed. The reverse of the donor's copy of the custody-and-control form is a good place for this information.

7.6.9 Procedures: Time Between Notification and Specimen Collection

Comment:

A few commenters responded to proposed changes regarding minimizing the time between notification and specimen collection. One commenter suggested that the NRC define "minimum" to be no more than one or two hours. Commenters noted specific procedural difficulties in assuring that the time be minimized. For example, this requirement could impose cost impacts and disrupt work if a supervisor does not assign the worker to duty so that the worker will be readily available for random test notification. Commenters also addressed the impact of the requirement on preventing subversion. (Identification numbers: 20; 29; 30; 5002)

Response:

Minimizing time from notification to testing is a minimal antiradical procedure. (See NUREG/CR 6470, Chapter 6, for a full discussion of this issue.) The NRC has chosen not to define "minimum" and continues to believe licensees should establish their own minimum standards. As stated in the Federal Register notice announcing the proposed amendments, many licensees have minimized the time (in some cases to essentially zero) and reported there were no problems, just different ways of doing things. If the NRC finds that licensees are not making an honest effort to minimize the time between notification and specimen collection, the NRC will consider defining a minimum time period.

In order to reduce disruption of critical tasks, the supervisor can wait to notify the individual until the task is completed. This flexibility in notification of the individual, however, should not be allowed to result in individuals only being tested at the beginning or end of a shift.

7.6.10 Procedures: Disposal of Chain-of-Custody Forms

Comment:

One commenter supports the proposed rule revision which stipulates that chain-of-custody forms recording specimens with negative test results and no FFD violations or anomalies may be destroyed after appropriate summary information has been recorded for program administration purposes. (Identification number: 20)

Response:

The NRC concurs and thanks the commenter for taking the time and effort to provide comments on the proposed rule revisions.

7.6.11 Procedures: Call In

Comment:

Three commenters objected to the proposed requirement that a person who is called in to perform an unscheduled working tour state whether he or she considers himself or herself fit to perform the tasks assigned. One of the commenters objected because such a statement is not required of people who report to work routinely and because the requirement implies that, when off duty, employees fail to maintain the capacity to work assigned tasks. Another commenter stated that this requirement may allow an employee to claim fitness issues and then refuse to perform undesirable tasks. This commenter agreed with a third commenter who maintained that the existing rule provides sufficient guidance because it requires a statement from the employee as to whether he or she has consumed alcohol within the length of time stated in the pre-duty abstinence policy. Another commenter inquired whether the intent of this requirement is for the employee to remain at home if he or she has consumed any alcohol. One commenter mentioned that the proposed requirement is currently a part of FFD policy. (Identification numbers: 7; 20; 30; 32; 5002)

Response:

When workers are not scheduled for work nor on-call, they are not expected to restrict their activities such that they would always be immediately fit for duty. For example, an individual may have a family or other obligation that prevents him or her from sleeping enough or may attend an event where he or she consumes alcohol. An example that occurred at one licensee involved an individual who had been involved in military reserve duties on top of excessive overtime on site prior to being unexpectedly called in for duty. The overtime and reserve activities had caused a level of fatigue such that the individual felt he would be incapable of properly performing his job. The NRC believes that most workers will respond appropriately based upon their evaluation of their fitness and that conditions other than consumption of alcohol should be considered. In cases where called-in employees consider themselves not fit to safely and competently perform their work because they have consumed alcohol or for other reasons such as fatigue or illness, they should not be required to travel to the work site. This will be in the interests of their own personal safety as well as the safety of plant operations. It will also eliminate the delay involved in replacing

a person when it is determined that he or she is not fit after arriving at the site. However, since these are business decisions, the NRC has removed “when contacted” from § 26.20(e)(1).

7.7 Other Testing Required

A few comments were also received in reference to other revised testing requirements and their impact on procedures, including NRC actions in response to program violations and other suggested wording changes.

7.7.1 Other Testing Required: Testing Equipment Calibration

Comment:

One commenter expressed concern that the NRC did not immediately take action when it became aware of the use of incorrectly calibrated testing equipment by some utilities. The commenter also expressed concern that more prompt action was not taken once it became known that an individual received an inaccurate positive test result from a licensee as a result of incorrect testing procedures. (Identification number: 28)

Response:

The NRC is concerned about the potential for an inaccurate test result and has a significant number of provisions to assure that such a result does not have an impact on anyone's career. In order to assure that individuals have adequate protection if there are failures in the system, the NRC has increased appeals support in the revised rule. The NRC considered this comment an allegation and has taken action to determine the true nature of the event(s) and whether appropriate actions were taken.

7.7.2 Other Testing Required: Suspension of Access Pending Verification

Comment:

One commenter asked the NRC to consider allowing a licensee to suspend the access authorization of an employee whose test result has come back from the HHS-certified laboratory as a laboratory confirmed positive test, but has not yet been verified by the MRO. The commenter pointed out that sometimes the individual may have access to the site before the MRO has had the opportunity to address the issue. (Identification number: 6005)

Response:

The NRC continues to believe that the licensee has sufficient flexibility to react to this situation under the rule as originally published.

7.7.3 Other Testing Required: Testing of Aliquots

Comment:

One commenter recommended that the proposed revision to section 26.24(d)(1) be changed so that the phrase “of aliquots” is omitted. The paragraph would read:(d)(1) All collected urine and blood specimens must be forwarded to a laboratory certified by the Department of Health and

Human Services (HHS), except that licensees may conduct screening tests of urine specimens to determine which specimens are negative and need no further testing. (Identification number: 36)

Response:

This change would not be acceptable. The use of the term “aliquots” is there to indicate that the on-site testing will use only an aliquot of the specimen and will not in any way contaminate or compromise the main specimen which would be sent to a HHS-certified laboratory for testing if the test of the aliquot were positive.

8.0 Suitable Inquiry

Several comments addressed the proposed suitable inquiry revisions. Some commenters raised questions regarding differences in inquiry procedures between the FFD suitable inquiry requirements and the access authorization program requirements. Several other comments were received requesting further clarification on suitable inquiry revised policies.

8.1 Suitable Inquiry Relationship to Access Authorization

A number of commenters requested further explanation regarding how the revised FFD suitable inquiry requirements associate with the Commission's access authorization procedures. Some issues of concern included the procedures for authorizing temporary unescorted access and the method and time requirements for reporting suitable inquiry information.

8.1.1 Suitable Inquiry Relationship to Access Authorization: Test Results Prior to 1990

Comment:

One commenter asked whether the NRC's proposal to limit the scope of suitable inquiries to five years would eliminate the potential harm that could be caused by drug test results of questionable accuracy obtained prior to January 3, 1990. (Identification number: 1)

Response:

This change may reduce the impact of such test results. However, such results or their impact on a previous access determination may continue to follow an individual if a removal resulted from the test even with the shorter period of background investigation because section 26.27(a)(1)(c) requires a determination if the individual was ever removed in accordance with a FFD policy.

8.1.2 Suitable Inquiry Relationship to Access Authorization: Temporary Unescorted Access

Comment:

Several commenters asked the Commission to modify the FFD rule's suitable inquiry requirement to be consistent with the temporary unescorted access provision of the access authorization program. Two commenters recommended that section 26.27(a) be modified to authorize licensees to grant temporary unescorted access pursuant to 10 CFR 73.56 when they have completed a suitable inquiry into applicants' activities over the past year, or have documented their best efforts to do so. This one-year suitable inquiry would be conducted while the licensee is implementing the full five-year suitable inquiry for the purpose of eventually granting permanent unescorted access. One of these commenters also recommended that licensees should be allowed to base these temporary access determinations on information received through electronic means but prohibited from granting temporary access to people who have previously violated a licensee's FFD policy. Two other commenters recommended that licensees be authorized to grant temporary unescorted access upon initiation, as opposed to completion, of a check with applicants' employers over the past one year. They mentioned an industry policy publication as currently sanctioning this approach. Another commenter noted that the NRC's access authorization program under 10 CFR 73.56 currently requires licensees to complete a one-year employment check before they can grant temporary unescorted access. Still another commenter

recommended that licensees be allowed to grant permanent unescorted access upon initiation, rather than completion, of the full five-year suitable inquiry. (Identification numbers: 3; 7; 10; 5002; 6004; 6015)

Response:

The access authorization requirements set forth in 10 CFR 73.56 and Regulatory Guide 5.66 (which all licensees have committed to implement) currently requires licensees to complete a one-year employment check, among other things, before they can grant temporary unescorted access. The NRC agrees that the FFD rule should provide for the granting of temporary unescorted access consistent with the access authorization requirements. Section 26.27(a) has, therefore, been revised to authorize licensees to grant temporary unescorted access when they have received and evaluated the past year's suitable inquiry results, or documented their best efforts to do so, initiated the balance of the five-year inquiry, and the applicant has received a negative result on a pre-access test. The NRC disagrees strongly with the implication contained in some of the comments that not even a modest effort to determine suitability is needed before granting access. Any licensee allowing unescorted access based solely on the initiation of a suitable inquiry would be in violation of § 26.27 as well as commitments to implement 10 CFR 73.56 by following Regulatory Guide 5.66.

The NRC stresses that licensees are to verify the accuracy of all employee answers to statements related to the history of substance abuse and to other answers to suitable inquiry questions. Accepting at face value employees' statements that they have no prior history of substance abuse is not acceptable. It should also be noted that such a "history" goes beyond positive drug tests. It must include, for example, instances of subversion and refusals to test. Also, a lack of a history of substance abuse is not a reason to allow an applicant for access to forgo pre-access testing.

The NRC is aware that obtaining information from short-term employers has sometimes proven difficult, especially when such employment is outside the nuclear power industry. The current wording of § 26.27 that requires licensees to complete suitable inquiries "on a best-efforts basis" provides licensees with sufficient flexibility when obtaining such information becomes too burdensome.

8.2 Other Suitable Inquiry

Several specific questions were raised by commenters regarding other proposed revisions to the suitable inquiry requirements. Questions ranged from requests for clarification as to what constitutes proof of no history of drug abuse to the specific types of information that are to be included in the suitable inquiry report. In addition, some commenters, for purposes of clarification, suggested revisions to the administration of the suitable inquiry process.

8.2.1 Other Suitable Inquiry: History of Substance Abuse

Comment:

One commenter thought the term "with a known history of substance abuse" in the proposed section 26.23(a)(2) was redundant and/or subject to misinterpretation and should be deleted. Another commenter said that this proposed rule change is unnecessary because the rule's current wording is adequate. (Identification numbers: 7; 20)

Response:

The NRC has made this minor clarification to reduce the occurrence of contractors failing to provide licensees with relevant and known information regarding an individual's background. Based on past experience, this is a prudent clarification. The phrase also prevents a contractor from being in violation if it does not know of an employee's history in this regard.

8.2.2 Other Suitable Inquiry: Short-Term Absence

Comment:

One commenter supported the revision that would allow a suitable inquiry not to be conducted when employees have been away from coverage of a FFD program for 30 days or less. (Identification number: 20)

Response:

Based upon information obtained after publication of the proposed rule, the NRC has decided to withdraw the proposed provision that would no longer require licensees to conduct a suitable inquiry for instances in which an applicant was not covered by an FFD program for periods of employment of 30 days or less. Licensee FFD personnel have indicated to the NRC that adverse FFD information is frequently obtained through checks of employment of 30 days or less. In those cases, employment was terminated for cause (oftentimes for substance abuse) before 30 days. Licensee FFD personnel also pointed out that under the proposed rule, employees could conceal their FFD problems by ensuring that their employment at any one site is less than 30 days, thereby avoiding both FFD testing as well as minimizing the possibility that a subsequent licensee would discover any previous for-cause termination occurring within the thirty-day period of previous employment. Furthermore, based upon the comments of the FFD personnel, the NRC now believes that there may be a concern with the employee who moves from one job to another after being terminated repeatedly for cause prior to 30 days. For these reasons, the NRC believes that a relaxation from the current requirement of conducting a suitable inquiry for all periods of employment would increase the risk to public health and safety. Accordingly, the NRC withdraws the proposed rule's provision allowing a licensee to skip a suitable inquiry for periods of employment of 30 days or less. This will avoid a situation in which workers have gaps in employment/unemployment during which employer knowledge regarding behavior affecting trustworthiness and reliability may be effectively concealed or otherwise not detected by the licensee's program. The NRC notes that the current requirement for a suitable inquiry does not apply to current employees who are temporarily away from the site and therefore not subject to a FFD program; instead the return-to-work provisions in the final rule in Section 26.27 apply to those employees who have not been subject to the licensee's FFD program for a period greater than 60 days. Finally, the NRC recognizes that obtaining information from short-term employers has sometimes proven difficult, especially when such employment is outside the nuclear power industry. The current wording of § 26.27 that requires licensees to complete suitable inquiries "on a best-efforts basis" provides licensees with sufficient flexibility when obtaining such information becomes too burdensome.

8.2.3 Other Suitable Inquiry: Verification of Employee's Statements

Comment:

One commenter asked whether employees' answers to suitable inquiry questions indicating no prior drug involvement will be sufficient for proof of no history of substance abuse that would allow employees to forgo preaccess tests. (Identification number: 5002)

Response:

Employees' statements are not sufficient in this regard. All answers to suitable inquiry questions must be verified. A "history" would go beyond positive drug tests--it would include, for example, subversion and refusal to test. A lack of history of substance abuse claimed by the employee is not sufficient to allow an individual to forgo preaccess testing.

8.2.4 Other Suitable Inquiry: Information to be Reported

Comment:

Two commenters asked for clarification as to whether Part 26 drug and alcohol test results and, in particular, information about an employee having previously produced a specimen below the allowable temperature range must be included in subsequent suitable inquiries. (Identification number: 5002)

Response:

Only violations of FFD policy should be reported. Any testing results that do not result in the determination of a violation are private and should not be reported.

8.2.5 Other Suitable Inquiry: History of Substance Abuse

Comment:

One commenter asked whether events such as DUIs that are outside the scope of Part 26 activities should be included in the history of substance abuse that is to be determined when licensees decide whether preaccess testing is required. (Identification number: 6008)

Response:

Events such as DUIs should be included in a person's history of substance abuse. These events are also covered under the access authorization program.

8.2.6 Other Suitable Inquiry: A Two-Step Process

Comment:

Several commenters recommended that the suitable inquiry requirement should involve a 2-step process. First, the licensees should obtain information from the individual regarding any prior history of abuse, the nature of that abuse, and the person's current situation. Second, the licensee should confirm the information provided with previous employers or other appropriate contacts. (Identification numbers: 14; 5002; 6008)

Response:

These two steps are implicitly required in the rule as revised. Both steps must be completed prior to the granting of unescorted access, although the requirements for the second step are relaxed (information pertaining to the past one year must be verified) for temporary unescorted access.

9.0 Chemical Testing

Several commenters responded to the NRC's proposed revisions to the chemical testing procedures. The NRC's request for comment on the use of non-instrumented testing devices, in particular, elicited a number of responses, the majority of which supported authorization of the devices. Other comments regarding on-site screening testing were also received. A wide range of comments were submitted regarding cut-off levels and several commenters expressed their opinions and provided suggestions regarding blind specimen testing procedures. Other chemical testing procedures were also addressed by commenters, many of whom provided suggestions for changes and requested clarification of particular practices

9.1 Use of Non-Instrumented Testing Devices

A number of commenters responded to the NRC's request for comment as to whether the use of non-instrumented testing devices should be authorized. The majority of commenters endorsed the proposal to authorize their use.

9.1.1 Use of Non-Instrumented Testing Devices: Positive and Negative Attributes

Comment:

Several commenters discussed quality control, performance standards (e.g., specificity, accuracy, reliability), and implementation issues of subversion prevention related to the on-site use of non-instrumented testing devices. Confidentiality and record keeping issues were also addressed. It was suggested that the concerns raised by the NRC are not specific to non-instrumented testing devices but apply to any currently used screening assay and that non-instrumented testing devices would be subject to the same NRC inspection and audit requirements and blind sample testing as currently approved testing instrumentation.

Several commenters recommended that the NRC authorize use of these devices as long as specific procedural standards and guidelines are developed, such as meeting the requirements of the Food and Drug Administration (FDA) 510(k) process for commercial distribution. Several commenters referred to published studies documenting the accuracy and reliability of the devices and others requested additional guidance for other sources of validation processes. Many commenters were in favor of the development of a conforming products list.

Several commenters discussed the benefits of such devices, commenting on the value of the immediacy of test results and the associated safety and security benefits, the cost savings, the ability to use the devices around the clock and in remote locations, the quicker in-processing time of contract workers, and the reduced skill level required to administer the tests. (Identification numbers: 2; 6; 7; 9; 10; 14; 15; 20; 25; 32; 6010; 6011; 6014; 6021)

Response:

The NRC appreciates the attention and consideration commenters have given this issue. The NRC has decided to prohibit the use of these devices to test for drugs of abuse pending an expected HHS/SAMHSA ruling on this issue. HHS has been tasked by Congress with validating the use of these devices. The Administrative Office of the U.S. Courts is also addressing the on-site use of non-instrumented testing devices and has contracted for an in-depth evaluation of these devices. At this point, it appears that false negative results, at least for some of the devices

to test for drugs of abuse, are still a problem. Until HHS makes a ruling on the acceptability of these devices to test for drugs of abuse in a workplace setting, the NRC will prohibit the use of non-instrumented testing devices for testing drugs. The relevant comments submitted to the NRC have been forwarded to HHS. The NRC will permit the use of non-instrumented devices in tests to determine the validity of specimens.

9.2 On-Site Testing

Some of the comments received about on-site testing pointed out its benefits. Others addressed on-site procedures when positive screening test results are found.

9.2.1 On-Site Testing: Benefits

Comment:

One commenter pointed out that use of on-site testing methods will decrease the time the entire testing process takes, from collection of the sample to analysis of the results. Also, fewer people handle the sample since transportation of the samples is necessary only for samples identified as positive by the initial screen. (Identification number: 9)

Response:

The NRC authorized on-site testing of specimens in the original rule for these and other reasons.

9.2.2 On-Site Testing: On-Site Screening Positives

Comment:

One commenter recommended that section 26.24(g) be revised to allow presumptive positive specimens from a licensee testing facility to be taken directly to gas chromatography/mass spectrometry (GC/MS) analysis by the HHS-certified laboratory. The commenter suggested that, if an unconfirmed positive specimen from a licensee testing facility cannot be taken directly to GC/MS confirmation, then the screening test performed at the HHS-certified laboratory should not be subject to any cut-off levels, but must merely verify the presence of drugs or drug metabolites. (Identification number: 36)

Response:

HHS-certified laboratories must perform screening testing on all specimens received and GC/MS testing on all specimens with a presumptive positive screening test; HHS is adamant that such a process is necessary to determine dilution ratios. Licensees may require HHS-certified laboratories to test all specimens with GC/MS testing regardless of the laboratory screening test results and can require laboratories to test at lower screening cut-off levels. Therefore, the NRC declines to permit licensees to bypass screening tests by HHS-certified laboratories and go directly to GC/MS testing of specimens that have a positive on-site screening test result.

9.3 Cut-Off Levels

A number of comments on cut-off levels were received. The proposal to raise the opiate screening and confirmation levels sparked a great deal of response, the majority of which was in opposition to the proposal, although some support for the change was also expressed. Other cut-off issues generating comment included 6-AM testing, the reduction of the THC cut-off level to 50 ng/ml, and the use of cut-off levels different from those required by the NRC.

9.3.1 Cut-Off Levels: Opiates and 6-AM

Comment:

There were a number of comments regarding the proposal to raise the opiate screening and confirmation levels. The majority of the commenters, including members of the American Association of Medical Review Officers, disagreed with the proposal to raise the opiate screening and confirmation levels, citing the high level of concern for safety in the nuclear industry. Other comments disagreeing with the change noted that there would be difficulties in identifying morphine, codeine, and, in some cases, heroin. Another commenter, in an effort to reduce some of the burden on MROs, suggested adding 6-AM to the test compounds measured during GC/MS confirmation. Some commenters cited literature and provided technical support for not raising the cut-off level— predicting that it would substantially increase false negatives. One commenter noted cases where an MRO identified potential impairment due to legal use of an opiate. Some commenters supported the change, giving evidence of the low percentage of opiate positives that are confirmed and the high cost of the high number of positive tests for opiates that were rejected by the MRO. Consistency with the HHS Mandatory Guidelines was also cited as a reason to raise the screening level for opiates, although some commenters pointed out that it is unclear when and if the HHS proposal on this matter will be implemented. One commenter recommended that requirements for 6-AM testing remain as they are, pending HHS action. (Identification numbers: 6; 7; 9; 10; 20; 23; 32; 36; 5003; 6014)

Response:

Based on the safety considerations presented by commenters, the NRC will maintain current cut-off levels for opiates at this time. This means that MROs will need to continue evaluating whether the presence of opiates, even if the specimen is not declared positive for opiates, presents a potential safety risk. To eliminate unnecessary confirmatory tests, the NRC will adopt the HHS policy with respect to testing for 6-AM. Testing for 6-AM will be required only when confirmed morphine concentrations exceed 2,000 ng/ml.

9.3.2 Cut-Off Levels: 6-AM Screening

Comment:

A number of commenters discussed the value of 6-AM screening in opiate testing. One commenter objected strongly to the proposed HHS Mandatory Guideline changes since the HHS proposal does not merely entail the adoption of an increased screening level for opiates. The HHS proposal also includes a requirement that the heroin metabolite 6-acetylmorphine (6-AM) be additionally detected prior to reaching the conclusion that substance abuse has occurred. It can be shown that this requirement alone will significantly reduce the likelihood that substance abuse will be successfully detected. (Identification numbers: 6; 7; 9; 6021)

Response:

The NRC will maintain current opiate cut-off levels at this time and adopt HHS policy with respect to testing for 6-AM. The NRC has carefully considered the potential risk to public health and safety posed by failure to identify opiate abuse. The NRC has determined that the protection of public health and safety necessitates the continued use of current cut-off levels for opiates. Based on the pharmacology of heroin metabolism, 6-AM is likely to be present only when morphine is present in the specimen and its concentration exceeds 2,000 ng/ml. Also see the discussion on 6-AM screening in the technical update in NUREG/CR-6470.

9.3.3 Cut-Off Levels: THC Screening Cut-Off Level

Comment:

Two commenters agreed with the proposed reduction of the THC screening cut-off level to 50 ng/ml. One supported this agreement with a discussion of the expected increase in the effectiveness of the program and the statement that “improving the ability to detect substance abuse is consistent with the general tenor of the NRC regulations.” In addition, this commenter noted that making the NRC cut-off consistent with the new HHS cut-off level will save the industry money. One commenter disagreed with the proposed change and commented that lowering the cut-off level for marijuana would have the same minimal impact as the NRC's drug testing program in general. (Identification number: 9; 20; 28)

Response:

The NRC concurs that the reduction of the screening cut-off level for THC is appropriate.

9.3.4 Cut-Off Levels: General Requests

Comment:

Several commenters provided general remarks regarding cut-off levels. One commenter suggested that the NRC should require the use of the HHS cut-offs for confirmed positive results. In addition, this commenter noted that if the NRC allows licensees to use more stringent cut-off levels, it should inform licensees that HHS certification does not apply to any test result derived from using cut-off levels other than those approved by HHS. This commenter also suggested that the wording of section 2.7(f)(1) be changed to read “Licensees may use the initial cut-off levels established by HHS or select more stringent cut-off levels.” Another commenter suggested that the wording on cut-off levels be changed to say that if licensees use more stringent cut-off levels, they shall request that the laboratory report the quantification for the confirmed positive tests. Finally, one licensee requested advice regarding the appropriate cut-off levels when alternative testing may be done after an accident (e.g., at a hospital). Note: the comments regarding the use of more stringent cut-off levels applied to both screening and confirmatory testing procedures. (Identification numbers: 17; 25; 36; 5002)

Response:

The NRC continues to rely on licensees to use the flexibility provided in the rule to use more stringent cut-off levels with good judgment. The NRC believes that the rule provides adequate information to licensees regarding the need to monitor HHS-certified laboratories and the additional requirements for auditing those laboratories when lower cut-off levels or additional drugs

are included in licensees' programs. The published proposed changes to section 4.1(b) of Appendix A to Part 26 reminded licensees that the HHS certification process does not include analysis of blood, tests for other substances, or use of lower cut-off levels. Provided the hospital permits access to its testing results by the licensee's medical staff, the rule permits consideration of any traces (limit of detection) of drugs detected by the hospital. If the hospital's test was consistent with the standards of Part 26 and the appropriate legal framework was in place, the licensee may consider the hospital's test a for-cause test.

9.3.5 Cut-Off Levels: Amphetamines

Comment:

One commenter objected to the HHS not revising its Mandatory Guidelines concerning the concentration of amphetamines. This commenter suggested that it would be more appropriate to use limit of detection testing for amphetamines, citing studies showing that many specimens that contained amphetamines had concentrations below this cut-off. (Identification number: 18)

Response:

The NRC will maintain current cut-off levels for amphetamines and will pass this comment on to HHS. HHS periodically reviews its cut-off levels and, on occasion, determines that it is appropriate to change them. NRC licensees are permitted to use lower cut-off levels than established by the NRC for amphetamines and other drugs.

9.3.6 Cut-Off Levels: Printing Error in Federal Register Notice

Comment:

One commenter noted that there was a mistake regarding the placement of amphetamine (as a heading) and the BAC level in the Federal Register notice in the table in section 2.7(g) of Appendix A. (Identification number: 36)

Response:

The NRC acknowledges these printing errors in the Federal Register notice. The correction has been made in the final rulemaking.

9.4 Blind Performance Testing

Several commenters provided responses regarding the proposed revisions to the blind performance testing requirements. The proposed requirements for diluting or adulterating blind performance testing specimens to challenge the laboratory's ability to determine specimen validity evoked a number of comments, both in favor and against the policy. Those in agreement emphasized the need for guidance in the specification of analyte concentrations. Others noted that a dilution specification would be difficult to implement in general and specifically with amphetamines. The revisions addressing the possible conflict of interest between blind sample specimen providers and collectors also elicited both opposing and supporting comments. A number of commenters addressed and provided suggestions for changes to the revised requirements for contracting with blind performance specimen vendors. Several commenters responded to the proposed increase in the percentage of positive blind specimens submitted. Other commenters sought guidance for implementing new procedures and clarification as to how

results of blind performance specimen testing should be interpreted. A number of suggestions regarding ways to ensure the quality of blind performance specimen testing and as well as other general recommendations were also received.

9.4.1 Blind Performance Testing: Spiking of Blind Performance Test Specimens

Comment:

A number of commenters objected to the proposed requirement that positive blind performance specimens be spiked to 60 percent of the cut-off, citing difficulties in implementation and enforcement. Commenters thought that this requirement demonstrated a lack of understanding of the intent of blind performance testing, which is to determine a laboratory's ability to detect a substance, not to verify quantification levels. Other reasons commenters were concerned about this requirement included: difficulties in determining the actual concentration in such a specimen, difficulties in maintaining spiked specimens at precisely 60 percent of cut-off level over a multi-week shelf life, lack of standard manufacturing criteria, and the licensees' lack of the necessary technical laboratory equipment to dilute samples to a specific level. In addition, some commenters felt that the NRC should not impose more stringent laboratory requirements than HHS. In contrast, one provider of blind performance samples agreed that some guidance is needed in the area of drug concentrations, noting that analyte concentrations vary widely across vendors. This commenter noted that this guidance should be developed with some input from experience. Another commenter noted that some difficulties and some advantages of defining a range of concentrations, but noted that there would be specific difficulties with amphetamines. Several commenters suggested that, if a range is defined, it should be consistent with all other regulations such as those of HHS and DOT. (Identification numbers: 7; 10; 14; 18; 20; 24; 25; 32; 36; 5002; 6005; 6006; 6010)

Response:

The NRC disagrees that the technical requirements for spiking specimens at 60 percent of the cut-off level after diluting them will be difficult to implement and enforce. The vendor that formulates the blind specimen should be capable of providing diluted or adulterated specimens spiked to plus or minus 10 percent of any value, whether it is the normal cut-off level or 60 percent of that level. Furthermore, many leading toxicologists have stated that they have had no problems doing this. The NRC continues to believe that assuring that the testing process must be based upon good quality blind performance test specimens, including assurances that the laboratory is able to determine specimen validity. Otherwise, licensee management will have no assurance that the laboratories are capable of conducting this very important element of the whole testing process.

The Commission has, however, decided to modify its originally proposed revision to the blind performance specimen requirements in § 2.8(e)(3) of Appendix A to permit licensees flexibility in the provision of adequate quality controls needed to support § 2.7(e). Section 2.7(e) will require licensees to have their HHS-certified laboratories screen test specimens of questionable validity at the lowest concentration level for which FDA-approved analytical kits are available. To accommodate this change, § 2.8(e)(3) has been revised to require that adulterated or diluted blind performance test specimens be spiked to between 60 and 80 percent of the licensee's cut-off levels.

9.4.2 Blind Performance Testing: Separate and Independent Performance Test Providers

Comment:

Commenters expressed opposing sentiments in response to the Commission's question as to whether providers of blind samples should be separate and independent from those performing collections, laboratories, those performing inspections, and MROs. One commenter noted that there have been no conflict of interest problems in this regard since the program's inception. Another commenter thought that, as long as blind performance test specimens are certified by immunoassay and GC/MS testing, there is no need for the provider to be separate and independent from contract providers of other laboratory functions for the licensee. This commenter also suggested that any such restriction should be the purview of HHS and not the NRC. On the other hand, two commenters agreed that these restrictions are necessary in order to avoid questions of conflict of interest and to assure that the laboratory does not pre-record results matched with blind specimens in its reporting system. (Identification numbers: 7; 10; 14; 18; 20; 25)

Response:

The NRC believes that it is not necessary at this time to require the independence of blind performance test specimen providers from the laboratory(ies) where those specimens will be tested. It will continue to confer with HHS regarding this issue.

9.4.3 Blind Performance Testing: “Initial 90-Day Period”

Comment:

Three commenters suggested that the NRC waive the requirement that a licensee must submit blind performance test specimens in an amount up to 20 percent of the total number of specimens submitted during the initial 90-day period of its contact with an HHS-certified laboratory if the licensee is establishing a contract with a laboratory that has been HHS certified for at least one audit cycle or has passed an initial blind performance period with another Part 26 licensee. It was suggested that these laboratories be allowed to begin their contracts using the 3-percent minimum level that is allowed after the initial 90-day period. (Identification numbers: 7; 20; 6004)

Response:

The NRC continues to believe that the initial period of contracting with a laboratory requires a rate of blind performance testing which is greater than the "maintenance" rate that is specified after initial performance results are obtained. This ensures that the system is working from the point of collection through HHS-certified laboratory testing. Therefore, this recommendation has not been adopted.

9.4.4 Blind Performance Testing: Change in Percent to Be Positive

Comment:

Three commenters requested clarification of how licensees should implement the proposed requirement that 50 percent of the blind performance test specimens that are positive must be positive in a distribution such that all the drugs are included in “approximately equal frequencies of challenge.” One commenter suggested that the percentage of tests per drug tested be in equal

proportion, e.g., for the standard five drug panel, one-fifth of the 50 percent blind specimens would be spiked with each drug in the test panel. One commenter asked for guidance as to how frequently licensees that do on-site testing and have extended drug panels must send to the laboratory blind performance tests representing their entire panel. The commenter asked whether this has to be done quarterly or if it can be done at equal frequencies over time. (Identification numbers: 7; 32; 6011)

Response:

There are a number of approaches that will adequately achieve an approximately equal frequency of challenge over time. The NRC provides licensees with the flexibility to determine the specific procedures as to how this requirement is to be met. The rule does not require that all drugs on the panel be included at equal frequency each quarter. However, the NRC would expect that a nearly equal frequency of challenge was achieved over several quarters.

9.4.5 Blind Performance Testing: Maximum and Minimum Percentages of Test Specimens

Comment:

One commenter supported the proposal to reduce the blind performance test minimum percentage from 10 percent to 3 percent after the initial 90-day period. However, the commenter suggested that for new laboratory contracts the NRC consider increasing the required percentage of positive blind performance test positives from 20 percent of the total number of specimens submitted to 40 percent or 50 percent. In addition, this commenter disagreed with the proposal to reduce the maximum number of blind performance test specimens required from 250 to 25, stating that HHS-certified laboratories' false negative rate cannot be adequately assessed with only 25 test specimens. This commenter also recommended a rule revision that would require blind test specimens be sent to HHS-certified laboratories evenly spaced throughout the month rather than bunched at the end of the month. (Identification number: 18)

Response:

Blind performance testing in licensee programs augments the testing required by HHS to certify laboratories. The number required is considered the minimum to assure that the process from collection through processing and reporting is sound. It is not intended to assess the laboratory's false negative rate. The NRC shares the commenter's concerns about false negatives, but declines to increase the minimum number of specimens for that purpose which it believes should be part of the HHS laboratory certification process. In response to the commenter's concern that blind performance test specimens be sent throughout a testing period, the NRC has added appropriate language to section 2.8(e)(2). (See also the discussion under 9.4.4.)

9.4.6 Blind Performance Testing: Increase in Percentage of Blind Specimens that Must Be Positive

Comment:

Several commenters responded to the proposed increase in the percentage of positive blind performance test specimens to be submitted from 20 percent to 50 percent under section 2.8(e)(3) of Appendix A. One commenter supported this increase. Other commenters disagreed with the

proposed revision, stating that increasing the number of blind specimens that must be positive for one or more drugs would burden the laboratories. (Identification numbers: 7; 18; 32; 6011)

Response:

The NRC does not agree that the increase in the percentage of positive blind performance specimens that must be positive for drugs will be a burden on laboratories because the total number of blind performance test specimens that must be submitted, including the number of positive test specimens, has decreased. The positive blind test specimen rate was selected, in consultation with HHS, to ensure that there are sufficient challenges to the laboratories after the total blind test specimen submission rate was reduced.

9.4.7 Blind Performance Testing: Unsatisfactory Blind Testing Result

Comment:

One commenter requested that the NRC clarify what constitutes an unsatisfactory testing result discovered in blind performance testing. For example, does a false negative (failure to identify the presence of a drug) constitute unsatisfactory performance? The commenter also asked who is to determine unsatisfactory performance. This commenter suggested that instituting a centralized performance assessment program would not be a cost effective or efficient means of measuring performance. Another commenter also requested clarification as to whether the NRC wants all false negative results reported to it, suggesting that without an elaborate data management system, this information may not be useful. The commenter suggested that guidelines for determining unsatisfactory performance be included in the rule and that the HHS Mandatory Guidelines regarding test errors be referenced. (Identification numbers: 18; 6008)

Response:

The NRC thanks the commenters for their thoughtful comments. In an analysis of unsatisfactory testing results published as Appendix D to NUREG/CR-5758 Vol. 3, Drs. Baylor and Bush of HHS defined unsatisfactory performance as follows: "Unsatisfactory testing results include both false negative and false positive results. A false negative test result refers to a specimen that is reported to be negative although the actual concentration of drug in the specimen is above the level used to determine whether a specimen is positive or negative. A false positive test result is defined as a specimen that does not contain any drugs that either tests positive for drugs (analytical false positive) or that is reported to be positive for drugs (administrative false positive). Unsatisfactory testing results also include other general problems in the drug testing process that by investigation have been linked to the improper manufacture, formulation, or packaging of the quality control specimens, the improper processing of the specimens on site prior to their shipment to the laboratory for testing, or inappropriate handling/actions by the Medical Review Officer (MRO). It should be noted that this is a double blind performance testing program (i.e., the laboratory does not know the identity or the content of the quality control specimens that are submitted to it by the licensee)." All testing errors and unsatisfactory performance as described in section 2.8(f) of Appendix A must be investigated and reported to the NRC. The NRC continues to rely on HHS and its laboratory certification program to ensure that the problems reported by the NRC's licensees result in proper corrective actions. The NRC sees no need to establish an elaborate data management system, clarify what constitutes an unsatisfactory testing result, or develop guidelines in that regard.

Unsatisfactory performance can be determined by the licensee (including the MRO) or the laboratory; however, the FFD rule does not require such determination. The test is whether, in the licensee's judgment, the unsatisfactory test result indicates the need for investigation and potential corrective action that will ensure the integrity of the testing process.

9.4.8 Blind Performance Testing: Quality Control of Specimens

Comment:

With regard to the quality of blind performance specimens, several commenters noted the potential for deterioration and the lack of clear quality control for these specimens. One commenter suggested that blind specimen sample preparation be registered with the FDA, or at least that these samples be prepared with the FDA "Good Manufacturing Practices" guidelines to assure that there is a paper trail for the specimens. In addition, the suggestion was made that auditing the manufacturers of these products be required. (Identification numbers: 7; 10; 18; 6011; 6021)

Response:

The NRC and HHS recognize that blind performance specimens have been a source of problems in the past (see NUREG/CR 5758 Volume 3, Appendix D). However, the NRC declines to require FDA registration or that specimens meet FDA "Good Manufacturing Practices" guidelines at this time.

9.4.9 Blind Performance Testing: *d* and *l* Isomer Testing

Comment:

One commenter asked whether blind specimens that have a positive GC/MS test result have to be tested for *d* and *l* isomers. (Identification number: 5002)

Response:

Blind performance test specimens must be treated exactly as all other specimens since the laboratory is not aware of which specimens are blind performance specimens. This means that blind performance test specimens testing positive for amphetamines should be tested for *d* and *l* isomers.

9.4.10 Blind Performance Testing: Blind Performance Test Specimens from Multiple Sites

Comment:

Three commenters were concerned about the NRC's expectation that licensees with multiple collection sites that use the same HHS-certified laboratory must submit blind performance test specimens to the laboratory from each of their sites. The commenters maintained that the remoteness of some sites makes collection of samples burdensome. Since the purpose of blind specimen testing is to ensure that the HHS laboratory correctly identifies the substances it is testing for, the commenters thought it unnecessary for each separate site to have to submit blind performance specimens. (Identification numbers: 10; 6005; 6010)

Response:

Submission of blind performance test specimens tests the entire testing process, from collection through determination of results by the MRO, not just the HHS-certified laboratory. Different facilities under the same management may perform differently. Therefore, each collection facility has always been required to send in its own blind performance specimens.

9.5 Other Chemical Testing Procedures

A number of comments were also received about other chemical testing procedures. For example, several commenters argued against the proposed policy to combine partial specimens in cases of insufficient volume. The time frame within which HHS-certified laboratories are to report results to the MRO drew dissenting responses and requests for clarification, as well. Several recommendations for changes to the procedures regarding specimen refrigeration, preparation, and transportation to the HHS-certified laboratory were also received. Revised split specimen collection procedures, in particular, elicited recommendations from commenters. Another testing procedure that drew both supporting and opposing comments included the proposal to require that positive amphetamine tests be tested for *d* and *l* isomers. Several comments were also received about other wording, flexibility, and testing issues.

9.5.1 Other Chemical Testing Procedures: Insufficient Volume Specimens

Comment:

Four commenters disagreed that partial specimens should be combined. One commenter stated that combining partial specimens would be inappropriate when one of the partial specimens (usually the first one) is suspected of being adulterated or substituted. Another commenter cited a DOT guideline which states that combining urine specimens increases the possibility of error or contamination in the collection process, and also is inconsistent with the HHS Mandatory Guidelines. A third commenter reasoned that combining partial specimens would lower the concentration of any drug that may be present because the donor is given fluids to complete a partial specimen. This commenter also noted that the requirement to seal each partial specimen may make chain-of-custody and control procedures more complicated since a second chain-of-custody form may be required. All three commenters recommended that partial specimens be stored separately and one suggested that the suspect samples be sent to an HHS-certified laboratory for testing. (Identification numbers: 3; 25; 36; 5002)

Response:

The NRC concurs that partial specimens should not be combined and has revised § 2.4(g)(11) of Appendix A accordingly. That section now requires each licensee to predetermine a quantity of urine that it will require of all people submitting specimens in its testing program. This quantity should take into account all analyses and reanalyses provided for in the licensee's FFD policy. It should provide for at least the 30 milliliters needed for testing at the licensee's HHS-certified laboratory plus an additional amount needed for testing for any drugs in addition to those specified in § 2.1(a) of Appendix A. Licensees that authorize split specimens or conduct onsite testing should also provide for these needs when determining the required quantity.

In cases where an employee produces a specimen of smaller quantity than that predetermined by the licensee, the specimen should be used to the extent possible to meet the testing requirements in the following order of priority: testing at the HHS-certified laboratory, provision for a split

specimen if authorized by licensee FFD policy, and on-site screening testing. That is, if the licensee conducts onsite screening testing and, for example, an employee can produce of specimen of only 30 to 35 milliliters, the licensee should not test that specimen on site but instead should send the specimen to its HHS-certified laboratory for testing. In this example, there would be no split specimen for the donor to challenge the results on the primary specimen. With respect to the combining of partial specimens, the NRC now believes that partial specimens should not be combined and no partial specimen should be discarded. Instead, specimens of less than 30 milliliters should be sent along with any subsequent specimen(s) collected during that collection process for testing at the HHS-certified laboratory and each specimen should be analyzed separately. The rule has been changed accordingly.

9.5.2 Other Chemical Testing Procedures: Time Period for Laboratory Report

Comment:

Several commenters discussed the length of time that is required for HHS-certified laboratories to report the results of drug tests to MROs. One commenter supported the NRC's proposed requirement that laboratory test results shall be reported to the MRO within four rather than five working days (six for suspected amphetamines). Another commenter questioned the HHS-certified laboratories' capability to submit the results of a positive test after only four days, particularly when conducting opiate and amphetamine testing which seems to be troublesome for the laboratories. The commenter also noted that section 2.7(h)(1) of Appendix A does not specify whether the 4-day turnaround is for the primary sample or the split sample. (Identification numbers: 20; 5002)

Response:

The NRC believes that a 4-day period is adequate for laboratories to complete testing and report results. The NRC agrees, however, that it is reasonable to have a 5-day window for laboratories to report the results of tests to MROs and prefers to be consistent with HHS and DOT requirements in this instance. The five-day turnaround time refers both to the primary and split specimen, which was clarified in section 2.7(k) of Appendix A by addition of the phrase, "... all other requirements of this appendix applicable to primary specimens shall also be applicable to split specimens."

9.5.3 Other Chemical Testing Procedures: Maintaining Specimen Quality

Comment:

Four commenters discussed the sections of the proposed rule that concern specimen refrigeration, preparation, and transportation to a certified laboratory. Two commenters recommended that the wording of section 2.4(i) of Appendix A be simplified to require collection site personnel to send specimens to a laboratory as soon as possible, rather than specifying 48 hours for receipt of the specimen by the laboratory. However, one of these commenters agreed that the time between the shipment and the screening test of a specimen should not exceed 72 hours, as the proposed rule revision required. The commenter maintained that the 72-hour requirement would ensure that there would never be a need to keep a specimen cool either at the collection site or during transit. Other commenters suggested that the proposed revisions regarding short-term refrigeration storage of specimens be approved as proposed. (Identification numbers: 20; 25; 32)

Response:

The NRC concurs that specimens should be sent to the laboratory as soon as possible and has retained the 48- and 72-hour limitations regarding shipment and HHS-certified laboratory screening times, respectively. However, the NRC has reviewed the requirements and added language to provide flexibility for unusual circumstances in order to assure that delays in shipment or testing do not invalidate specimens. Licensees should not need to use this flexibility on a routine basis, however. For example, it may be difficult to assure that specimens collected and shipped immediately prior to a holiday weekend arrive at the laboratory within 48 hours. These specimens should be collected normally, refrigerated, and then sent to the laboratory after the holiday.

9.5.4 Other Chemical Testing Procedures: Shipment of Split Specimens for Testing

Comment:

Three commenters discussed the proposed revision regarding shipment of split specimens for testing. The commenters maintained that requiring a medical review officer to forward a split specimen on the same day that the request is made may not be possible if the request is received late in the day. The commenters suggested that this provision be reworded to accommodate requests made in the afternoon or on a Friday, when the earliest receipt by a certified laboratory would be on a Monday. (Identification numbers: 20; 30; 32)

Response:

The NRC has determined that there are a number of valid reasons that split specimens may not be able to be shipped to a laboratory on the day of the request. The rule has been changed to require the specimen to be sent as soon as practicable, but in no case longer than three week days from the day of the request. The NRC expects licensees to assure that any delay does not adversely affect an employee.

9.5.5 Other Chemical Testing Procedures: Split Specimens

Comment:

Several commenters addressed the proposed new collection procedures for split specimen collection. Two commenters supported the proposed reduction in the split specimen quantity from 60 to 30 milliliters. (The NRC proposed at least 30 milliliters for the primary specimen and 15 milliliters for any split specimens.) A third commenter suggested that section 2.7(k) of Appendix A specify the amount in milliliters as section 2.4(g)(11) does. In contrast, one commenter noted that the procedures for analyzing split specimens in section 2.7(k) may conflict with the collection procedure outlined in section 2.4(g)(11). As then written, section 2.7(k) stated that, at the discretion of the licensee, urine specimens may be split into two parts, the primary specimen and the split specimen, each being one half of the original specimen. Proposed revisions to section 2.4(g)(11) would require an unequal splitting of the original specimen into 30 ml. for the primary and 15 ml. for the split specimen. The commenter recommended that section 2.7(k) of Appendix A be reworded to eliminate this inconsistency. (Identification numbers: 20; 30; 32; 36)

Response:

The NRC appreciates these comments and suggestions and having this discrepancy brought to its attention. Section 2.7(k) of Appendix A has been revised to address these comments. See also response to Summary Comments 7.6.6.

9.5.6 Other Chemical Testing Procedures: Testing for *d* and *l* Isomers

Comment:

Several commenters responded to the proposed requirement that specimens that have a positive GC/MS test result for amphetamines must be tested for *d* and *l* isomers. Some commenters supported the new requirement. Because amphetamine positives are so few, these commenters predicted that the additional test would have minimal impact on licensees and may serve to spare an employee with a false positive from the stigma of questioning. Other commenters disagreed with the proposed new policy. Some of these commenters maintained that some laboratories use a second testing device that can distinguish between a true and a false positive due to legal medications. These commenters argued that additional tests would increase costs and lengthen turn-around time. Another commenter wondered if HHS-certified laboratories could be expected to provide routine quality control and inspection criteria when *d* and *l* isomer testing is performed. (Identification numbers: 7; 25; 30; 32; 5002)

Response:

After weighing the potential benefits and costs, the NRC has decided to adopt HHS's Technical Advisory of March 11, 1991, and require that specimens having a positive GC/MS test result for amphetamines be tested for the *d* and *l* isomers. This test is essentially another GC/MS confirmation test to determine if legal drugs containing amphetamine compounds caused the positive drug test. In some cases the MRO may be able to look at the concentration levels for amphetamine and methamphetamine obtained during the GC/MS confirmation testing, as well as information provided by the donor, to make the determination. Frequently, however, additional information is required. In these cases, it is currently necessary for the MRO to request the additional GC/MS test for the *d* and *l* isomers. This can be done on a case-specific basis or under a blanket request.

The NRC's adoption of this requirement in effect mandates a blanket request which will expedite the availability of information to the MRO. This, in turn, should permit more timely responses to potential safety problems. Assuming that MROs are currently obtaining information on *d* and *l* isomers from all GC/MS positives for amphetamines, the additional burden on licensees is expected to total only a few tests per year industry wide, a number that will create an insignificant additional cost.

The NRC also notes that information obtained from HHS indicates that the commenter's assertion that some laboratories use a second testing device that can distinguish between a true and false positive due to legal medications is mistaken. The general laboratory practice is to use the EMIT screen, which has some cross-reactivity problems, for the screening test, then rescreen specimens with a positive screening test result with the Abbot TDx, which is more specific for the *d* isomer and has less cross-reactivity. This double screening for amphetamines is followed by GC/MS testing. This process would not eliminate prescribed amphetamines, but would eliminate most cross-reactivity caused by over-the-counter medications.

9.5.7 Other Chemical Testing Procedures: Testing for "Illegal Drugs"

Comment:

One commenter suggested that the term "illegal drugs" in section 2.1(b) of Appendix A, be changed to "drugs included in Schedules I or II of the Controlled Substances Act," in order to include prescription, and legal drugs. The commenter also recommended that, if a licensee wishes to test for any drugs or substances not included in the above act, this should be specified on the custody and control form. Doing so recognizes that an HHS-certified laboratory is only permitted to test regulated specimens for the drugs listed in the HHS Guidelines and may not conduct a comprehensive test for other drugs without specific guidance from a client and may not conduct a comprehensive test for other drugs without specific guidance from a client. (Identification number: 25)

Response:

The NRC has defined "illegal drugs" to include "any drugs included in Schedules I through V of the Controlled Substances Act." Section 2.1(b) of Appendix A has been revised to make it clear that licensees can and should test for drugs they suspect of being abused in any for-cause test, return-to-duty test after removal from access under section 26.24(b), any test of an individual who is in a follow-up testing program, or analysis of any specimen suspected of being adulterated or diluted, substituted, or tampered with by any other means.

9.5.8 Other Chemical Testing Procedures: Retesting at a Second Laboratory

Comment:

One commenter recommended that the NRC require that specimens confirmed as positive be retested at a different HHS-certified laboratory. (Identification number: 28)

Response:

The NRC concurs that any additional testing (retesting and testing of split samples) of a laboratory confirmed positive specimen should be done at a second laboratory. Other than requiring the testing of split samples be at a second laboratory, however, the NRC has decided not to mandate retesting at a second laboratory.

9.5.9 Other Chemical Testing Procedures: Flexibility to Add Substances and Change Cut-Off Levels

Comment:

One commenter recommended that the NRC discontinue allowing licensees to add substances to the panel of substances for testing, and then independently assign cut-off levels for the new substances. Instead, the commenter recommended that the rule require licensees to petition the NRC for a rule change in order to add a substance and corresponding cut-off level. The commenter maintained that petitioning the NRC would inform the industry and interested public about the new substance, and also allow them the opportunity to review and comment on its proposed addition to the testing panel. (Identification number: 17)

Response:

The NRC continues to believe that licensees can monitor the appropriateness of testing for additional substances and the appropriate cut-off levels for those specimens without initiating a rulemaking or NRC petition process. This is especially true where abuse of some substances is limited to certain regions of the U.S.

9.5.10 Other Chemical Testing Procedures: Subpart D / Certification of Laboratories

Comment:

One commenter noted that it should be made very clear throughout the rule that HHS does not certify a laboratory to (1) test blood specimens for alcohol, (2) test substances not in the HHS drug panel, or (3) use cut-off levels other than those specified by the HHS Mandatory Guidelines. (Identification number: 25)

Response:

The NRC believes that this has been made sufficiently clear to licensees in section 4.1(b) of Appendix A, but will assure that this is highlighted when the revised rule is published in the Federal Register.

10.0 Alcohol Issues

Proposed revisions to the alcohol testing procedures generated a number of comments. Issues of concern ranged from general testing issues and procedures (e.g., possible alternatives to alcohol testing techniques and the policy of conducting a blood alcohol test) to the proposal to require back extrapolation of alcohol tests between 0.02 and 0.04 percent blood alcohol content (BAC).

10.1 Alcohol Testing

A number of general alcohol testing issues were raised by commenters. For example, several comments and suggestions were received regarding alternative techniques for testing alcohol. The use of non-evidential grade breath analysis equipment was discussed by many commenters. Other commenters recommended that DOT screening and confirmation procedures be adopted. Procedures for testing the second breath specimen were also discussed by commenters, with some requesting clarification about confirmation of positive alcohol tests.

10.1.1 Alcohol Testing: Alternative Techniques

Comment:

Several commenters responded to the Commission's question as to whether there are any alternative techniques for testing for alcohol that should be considered for adoption. One commenter stated that there are no alternative techniques that the NRC should consider for testing for alcohol. Three commenters stressed the importance of using National Highway Traffic Safety Administration approved evidential grade breath analysis equipment. Two other commenters recommended that non-evidential breath testing devices should be approved for initial alcohol screening as they are in the DOT regulations. Any device that meets the Conforming Products List for breath alcohol instruments would be acceptable if this suggestion was adopted. Another commenter supported evidentiary breath testing but also recommended that the 7110 MKIII be allowed for use in confirmatory, or in both screening and confirmatory, breath testing. (Identification numbers: 7; 10; 11; 14; 20; 32)

Response:

The NRC believes that the current requirements for use of NHTSA approved devices is appropriate, and will continue to require the use of such devices. All NRC regulated programs currently have such devices in use. The DOT provides more flexibility for initial testing due to the nature of the industry it regulates, which requires more mobile testing mechanisms. Such mobility is generally not an issue in NRC regulated programs.

With regard to the initial alcohol screening procedures, the NRC is satisfied with the current requirements and the NHTSA's evidential grade breath analysis equipment, and believes that the use of non-evidential grade equipment may lead to false negative test results. Therefore, the alcohol screening procedures will not be changed to permit non-evidential grade equipment.

10.1.2 Alcohol Testing: DOT's Procedures

Comment:

Three commenters recommended that the NRC adopt the DOT's alcohol screening and confirmation procedures. One of these commenters maintained, in the interests of cost effectiveness, that a second evidential breath measurement instrument should not be required for the alcohol confirmatory test. A fourth commenter noted that having to operate under both the NRC and DOT breath alcohol testing requirements creates unnecessary complications for licensees. (Identification numbers: 7; 11; 15; 36; 6010)

Response:

The NRC believes that the rule's alcohol testing requirements have been successfully implemented by its licensees and are not in need of significant revision. The added protection of individuals warrants the use of two evidential breath measurement devices prior to a confirmed positive test result. However, the NRC has, in the interests of reducing the burden on individuals of being covered by redundant testing programs, allowed the acceptance of certain test results under other programs in section 26.2(f).

10.1.3 Alcohol Testing: Alcohol Testing Procedures

Comment:

Two commenters agreed that a second breath specimen should not be taken if the result of the first breath specimen proves negative. One of these commenters, however, recommended that a breath specimen should be considered negative if it is less than 0.04 percent rather than less than 0.01 percent BAC. As noted in the previous comment (section 10.1.2), one commenter thought that there is no value to repeating the initial breath test and then confirming those results on a second evidential breath testing device, regardless of the test results. (Identification numbers: 20; 32; 36)

Response:

The NRC has considered these comments and continues to believe that the rule as proposed best meets its responsibilities to protect public health and safety while continuing to safeguard the individual's rights.

10.1.4 Alcohol Testing: Redesignation of Rule Section

Comment:

One commenter questioned the need to redesignate the current section 2.7(o) in Appendix A, which requires the use of evidential-grade breath alcohol analysis devices, as section 2.7(p). (Identification number: 36)

Response:

A new section 2.7(e) has been added. This revision, and others like it, maintains the appropriate sequencing of subsequent sections in light of new, removed, or relocated sections.

10.1.5 Alcohol Testing: Clarification of Confirmatory Testing for Alcohol

Comment:

One commenter asked for clarification regarding confirmatory testing procedures for alcohol. Would the second breath test be the confirmatory test and is a blood test used only in the appeals process? (Identification number: 5002)

Response:

Positive results from tests of two breath specimens (the third and fourth specimens tested) done on the second, evidential-grade breath alcohol analysis device are considered the confirmed positive test result. Individuals may, at their discretion, immediately request a blood test for alcohol to be used in an appeal. The rule does not permit the individual to use the result for any other purpose.

10.2 Extrapolation

The proposed requirement that alcohol test results between 0.02 percent and 0.04 percent BAC be forwarded to the MRO for back extrapolation to determine whether the person had an impermissibly high blood alcohol content while on duty elicited a number of responses from commenters. While the majority of commenters opposed the proposed requirement and recommended that it be eliminated from the rule, a few commenters supported the proposal to require extrapolation and requested additional guidance as to how the procedure should be carried out. Some commenters made recommendations and raised questions regarding administrative and disciplinary actions that would result from an alcohol back extrapolation. Other commenters provided alternatives to the alcohol extrapolation procedure.

10.2.1 Extrapolation: Criticism of Technique

Comment:

Sixteen commenters recommended elimination of any requirement for back extrapolation. They cited reasons such as the variability with which different people metabolize alcohol, the likelihood that disciplinary actions after use of extrapolation would be challenged due to that variability, and the fact that the DOT rule does not require extrapolation. One of these commenters recommended that, if administrative or disciplinary action is to be taken based on an alcohol test in the 0.02 percent to 0.039 percent BAC range, the action should at most be the removal of the employee from safety-sensitive work for a period of 24 hours, as the DOT requires. Two other commenters suggested that an employee whose percent BAC is in this range be referred to his or her respective EAP for evaluation. Another commenter warned that requiring extrapolation would provide a disincentive to supervisors for requiring employees to undergo for-cause tests. Another commenter agreed that back extrapolation should not be required, but contended that licensees should be allowed the option to use it in their programs if they wish. (Identification numbers: 1; 7; 8; 10; 12; 15; 17; 20; 23; 28; 29; 6005; 6010; 6011; 6014; 6017)

Response:

The NRC proposed the back extrapolation requirement because it was concerned that some licensees have not taken appropriate action after obtaining alcohol test results just below 0.04 percent BAC after the tested employee has been at work for several hours. These results allow very little doubt that the employee has had an unacceptably high BAC, and has probably been impaired, at some time during the work period. These situations must prompt an investigation as to whether the employee has violated the licensee's FFD policy. Although the NRC continues to consider back extrapolation to be an appropriate technique to deal with such situations, it has determined that it is desirable to set a standard that does not require an MRO's evaluation.

In place of a back extrapolation requirement, the NRC has revised § 26.24(h) to adopt a standard for declaration of a positive test result based on BAC levels above 0.02 percent. This section now requires that findings of BAC levels of 0.03 percent or greater after the worker has been on duty for one hour or 0.02 percent or greater after the worker has been on duty for 2 hours be declared violations of the licensee's FFD policy. This revision eliminates the need for the MRO to perform back extrapolation. Licensees should assure that their employees are aware of this rule change and its implications. Licensees are also reminded that they should continue to make their employees aware of the individual differences in alcohol metabolism, the effects of food on metabolism rates, and other physiological variables that effect blood alcohol content.

10.2.2 Extrapolation: Support for Technique

Comment:

Five commenters agreed with the proposed revision to require extrapolation. They cited reasons including the belief that extrapolation would improve testing program effectiveness and the confidence in the technical merit of back extrapolation techniques. (Identification numbers: 8; 30; 32; 5003; 6013)

Response:

While the NRC agrees that extrapolation is an appropriate technique, it has decided to provide specific levels to eliminate the need to involve a MRO. See the response to Summary Comment 10.2.1.

10.2.3 Extrapolation: Need for Guidance

Comment:

One commenter pointed out that without further technical and procedural guidance, MROs will have difficulty in fulfilling the back extrapolation requirement. One commenter specifically asked the NRC to provide an acceptable value for the extrapolation factor that should be used to calculate the amount of alcohol present at the start of a work shift. Another asked for guidance as to whether workers waiting for extrapolation to be completed are to be prohibited from having unescorted access during this time. The third comment requested that standards for doing extrapolation be included in the rule. (Identification numbers: 8; 5002; 6005)

Response:

The NRC does not agree with the comments regarding the technical difficulties of back extrapolation by an experienced MRO, but has revised the rule to provide specific guidance and to eliminate the requirement for MRO involvement. See also the response to Summary Comment 10.2.1.

10.2.4 Extrapolation: Need for Sanctions

Comment:

One commenter recommended that instead of using back extrapolation, a licensee should be required, at a minimum, to take action against an individual. The commenter suggested that the specific action should be at the discretion of the licensee, but it should be sufficient to deter the use of alcohol. Another commenter recommended that a confirmatory breath test of 0.04 percent BAC or greater at the time of testing be considered a violation of FFD policy and that there be no consideration of what the alcohol test results may indicate about employee's BAC earlier in the scheduled working tour. (Identification numbers: 10; 24)

Response:

See the response to Summary Comment 10.2.1.

10.3 Other Alcohol Issues

Several other alcohol issues were addressed by commenters, as well. These issues included the benefits of drawing blood in alcohol testing. One issue that received particular attention was the proposed requirement to collect blood specimens for appeal purposes. Responses regarding this policy were varied, with some in favor of the change and some against it. The pre-duty abstinence period was also discussed, as were other alcohol related procedures, such as the sanctions and actions to be implemented or taken in response to alcohol violations.

10.3.1 Other Alcohol Issues: Collection of Blood Specimens

Comment:

Several commenters recommended elimination of the proposed requirement to collect blood specimens at the request of employees for purposes of appeal. One commenter supported the use of blood specimens for appeals. Those opposing the use of blood specimens for appeals cited the cost of having to maintain equipment to support blood collection relative to what they argue to be very small utility of doing so, potential problems with blood borne pathogens, and the existence of alternative alcohol evidential grade testing methodologies that can be used for purposes of appeal. One commenter suggested limiting blood testing to serious post-accident cases. Another commenter pointed out that eliminating the blood draw provision would create consistency with the DOT drug and alcohol testing rule. The commenter supporting the use of blood stated that blood tests provide workers with a safeguard in cases where breath alcohol devices may be defective and support sanctions when those sanctions are challenged in court. (Identification numbers: 7; 15; 20; 23; 6004; 6009; 6010; 6011; 6013)

Response:

The NRC recognizes the difficulties associated with blood collection for alcohol testing and the limited usefulness of such testing. The NRC is aware that it is unlikely that a blood test would result in a different outcome than the confirmatory test using an evidential-grade breath alcohol analysis device. Nevertheless, the NRC continues to believe that the provision for this testing provides desirable reassurance to individuals regarding their appeal rights and increased legal defensibility of all positive alcohol results, including those appealed without the drawing of blood.

10.3.2 Other Alcohol Issues: Pre-Duty Abstention Period

Comment:

One commenter pointed out that one of the most difficult issues in controlling alcohol use in the workplace is the pre-duty abstention period. While DOT and FAA designate different minimum periods of pre-duty abstinence than the NRC's 5-hour policy, the commenter maintains that there is nothing "magic" about these periods. (Identification number: 5003)

Response:

The NRC agrees that there is nothing magic about a specific pre-duty abstention period. It is intended to be a "standard" for the average employee who has not consumed a large quantity of alcohol, recognizing that food and sleep may prolong the metabolizing. For these reasons the NRC encourages licensees to inform their employees that regardless of the abstention period, any BAC greater than 0.04 percent when they arrive at work, greater than 0.03 percent after one hour on duty, or greater than 0.02 percent after 2 or more hours on duty is a violation of licensee FFD policy.

10.3.3 Other Alcohol Issues: Objection to Required Sanctions for Alcohol

Comment:

Commenters objected to the proposal to make sanctions for alcohol equivalent to those for illegal drugs. One objected to lumping alcohol and prescription drugs with illegal drugs. Another commenter recommended against the proposed rule change which adds alcohol confirmed positive tests to the requirement in section 26.27(b)(3) that a confirmed positive drug or alcohol test must result in at least a 14 day removal from duty and referral to an EAP. Instead, alcohol and/or prescription medication misuse should continue to be handled on a case-by-case basis. (Identification number: 7, 15)

Response:

The NRC has always intended that licensees have sanctions for alcohol abuse that will adequately deter such abuse. Noting the continued positive alcohol test results and some licensees' lack of effective sanctions for alcohol abuse, the NRC proposed to establish minimum sanctions for alcohol abuse. The NRC's review of licensee FFD program performance and the relevant literature continue to suggest that the minimum action needed to deter alcohol abuse is a 14-day removal from duty, referral to the EAP, follow-up testing, and knowledge that a second confirmed positive test result will lead to denial of unescorted access for a minimum of three years. Therefore, the Commission has decided to retain this change to the rule.

With respect to sanctions based on back calculation of alcohol BAC, the NRC has decided not to require back calculation, as discussed in item 19, above. The same sanctions that apply to any other alcohol-related violation will apply in these cases.

10.3.4 Other Alcohol Issues: BAC Levels Between 0.02 Percent and 0.04 Percent

Comment:

One commenter suggested that MROs be required to review BAC readings between 0.02 percent and 0.039 percent rather than 0.04 percent because a reading of 0.04 percent would be considered a positive test result. (Identification number: 23)

Response:

The NRC believes the revisions to this rule change deal with this issue. See summary response to Summary Comment 10.2.1.

10.3.5 Other Alcohol Issues: Procedures Regarding Blood Specimens

Comment:

Two commenters agreed with the NRC's proposals regarding particular procedures for using blood specimens as a means of appealing confirmed positive alcohol tests. One of these commenters agreed that licensees should be able to consider any detectable quantity of alcohol in these blood specimens as FFD violations. This is appropriate because of the time lag between the breath alcohol reading and the taking of the blood specimen. The other commenter agreed that the length of time between confirmed positive breath test and the drawing of the blood specimen should be minimized. A third commenter asked the NRC to clarify whether the blood draw would be optional if the breath test reading is between 0.02 percent and 0.04 percent and the MRO has determined a confirmed positive using extrapolation. (Identification numbers: 30; 32; 5002)

Response:

The NRC appreciates these comments. With regard to BAC levels of 0.02 percent to 0.04 percent, any violation of licensee FFD policy will require that the option of requesting a blood test be offered.

11.0 Subversion

Several commenters made recommendations regarding the proposed requirements to prevent and detect subversion. These commenters addressed the proposal to require limit of detection (LOD) testing, new and revised specimen validity determination procedures, the revised specimen temperature range, and several other subversion prevention/detection issues.

11.1 Limit of Detection (LOD)

A number of commenters responded to the proposal to require LOD testing. Commenters opposing the policy cited concerns about increased costs, the technical defensibility of the procedure, problems of cross-contamination during testing, the fact that HHS had not sanctioned the policy, and the possibility of different standards between laboratories. Other commenters supported the proposed requirement, arguing that it is an effective and technically defensible procedure. A few commenters agreed with the practice, but only for follow-up tests and appeals. Some commenters requested procedural and protocol guidance and raised questions regarding how positive test results are determined using LOD.

11.1.1 Limit of Detection (LOD): Costs of LOD Testing

Comment:

Four commenters recommended that limit of detection testing should not be required, or should be left to licensee discretion, because of the increased costs that such testing would create. One commenter estimated that this requirement would result in increased costs of between \$125 and \$275 per specimen and increase the turn-around time to get test results. Confirmation testing at limit of detection for all five drugs, however, would be too expensive. (Identification numbers: 7; 10; 29; 6017)

Response:

After reviewing the costs of LOD testing in response to these comments, the NRC continues to believe that testing specimens determined to be outside of specification will be a cost-effective means of protecting those being tested from incorrect conclusions about the validity of their specimens. It will also be an effective deterrent to substance abuse. The testing process continues to provide for screening testing to reduce the cost of GC/MS testing. LOD testing will be required for a drug identified through a screening test that is compared to a negative control. This procedure should not be significantly more expensive than normal testing.

11.1.2 Limit of Detection (LOD): HHS Procedures for LOD Testing

Comment:

Several commenters recommended that testing at limit of detection should not be required until HHS sanctions such testing and develops scientific procedures that would support a licensee taking employment action based on testing at limit of detection. (Identification numbers: 10; 5002; 6017)

Response:

Each HHS-certified laboratory has a LOD based on laboratory performance tests. HHS-certified laboratories are thus able to identify drug metabolites at lower concentration levels found in dilute specimens in a sufficiently forensically sound manner at this time. Furthermore, the HHS Mandatory Guidelines permit testing to determine the validity of a specimen (see section 2.1(c) of the HHS Mandatory Guidelines) and permit LOD testing to confirm the presence of the drug or drug metabolite during retesting (see section 2.4(i) of the HHS Mandatory Guidelines).

11.1.3 Limit of Detection (LOD): Technical Defensibility

Comment:

Two commenters stated that limit of detection testing should not be required because such testing may not be technically defensible. One commenter noted that HHS-certified laboratories do not have consistent limits of detection because of differences in sophistication of equipment and laboratory personnel expertise. Another commenter stated that limit of detection testing may not be appropriate for screening tests because few HHS-certified laboratories have established limits of detection for screening specimens. One commenter was concerned about defending an action outside of HHS recommendations. (Identification numbers: 10; 18; 6005)

Response:

Each HHS-certified laboratory has a limit of detection based on its ability to reliably detect the lowest concentration of an analyte which will vary from lab to lab and may vary over time due to several factors, such as the method chosen to extract the drug(s) from the urine and the method chosen to ionize drug molecules. LOD levels are established for GC/MS testing but not for screening testing. HHS-certified laboratories are thus able to reliably identify drug metabolites at the low concentration levels found in dilute specimens in a forensically valid manner. It should also be noted that the HHS Mandatory Guidelines currently permit testing to determine specimen validity (see section 2.1(c) of the HHS Mandatory Guidelines) and also permit LOD testing to confirm the presence of the drug or drug metabolite during retesting (see section 2.4(i) of the HHS Mandatory Guidelines).

In recognition that LOD testing applies only to GC/MS testing, the NRC has modified the proposed new § 2.7(e) of Appendix A to require licensees to subject specimens that are determined to be of questionable validity that show evidence of dilution to screening testing using FDA-approved analytical kits having the lowest concentration levels marketed for the screening technology being used. The responses of the questionable donor specimens must be compared to the acceptable range of negative screening control responses and those that respond greater than the negative control response (e.g., indicating the presence of drugs) must be subject to LOD confirmation testing. The important point is that specimens that are determined to be of questionable validity should not be tested at the normal cut-off levels. Also, specimens that are found to be out of specification may be GC/MS tested at LOD regardless of the screening test result if the MRO continues to question the reason for the specimen dilution. GC/MS testing at LOD of the specimens that are found to be out of specification should be performed regardless of the screening test result if the MRO determines that the dilution is the result of a subversion attempt. Differences in LOD capabilities across HHS-certified laboratories should not affect the defensibility of LOD testing results. These are unique to each laboratory and capacities of equipment and may vary from day to day, as reagents are changed, etc. However, the LOD is legally and technically defensible because it is the lowest concentration which can be reliably detected by that laboratory

on that day. However, licensees should consider HHS-certified laboratories' LOD capabilities when selecting their testing laboratories.

11.1.4 Limit of Detection (LOD): Cross Contamination

Comment:

Two commenters raised technical issues regarding limit of detection testing. One commenter said that such testing would create significant problems in laboratories with regard to preventing possible cross-contamination and carryover between aliquots during the testing. Another wondered why LOD is not used if the creatinine level is available when specific gravity is less than 1.001. (Identification numbers: 25; 5002)

Response:

The NRC believes that HHS-certified laboratories are capable of preventing cross-contamination of specimens when using LOD testing. HHS-certified laboratories are capable of reliably testing at specific LODs that are substantially lower than the standard cut-off levels for GC/MS testing.

11.1.5 Limit of Detection (LOD): Using LOD for Reanalysis for an Appeal

Comment:

One commenter suggested that limit of detection testing would be appropriate only when specimens are being reanalyzed on appeal because prolonged storage and/or freezing can lower the metabolite level in specimens. (Identification number: 10)

Response:

The NRC agrees that LOD testing may appropriately be used when specimens are being reanalyzed on appeal. However, the NRC also believes such testing is appropriate in other cases, as described in the rule, because continuing to use cut-off levels when someone has deliberately subverted the testing process to produce a concentration level below the cut-off level is to ignore this potential for subversion and the potential threat to public health and safety.

11.1.6 Limit of Detection (LOD): Methamphetamine Testing

Comment:

One commenter stated that experience with limit of detection testing of specimens that have been screened positive for methamphetamine has proven to be effective and technically defensible. (Identification number: 6011)

Response:

The NRC appreciates the commenter providing this information.

11.1.7 Limit of Detection (LOD): Follow-Up Testing

Comment:

One commenter supported the use of testing at limit of detection when employees are being tested in follow-up programs. This commenter cautioned, however, that evidence of an original marijuana use could cause a positive return-to-duty test result if the specimen was tested at the laboratory's limit of detection. The commenter stated that this problem can be addressed by requiring that the level of marijuana metabolite found in the return-to-duty tests be lower than the original test result rather than below the level of detection. (Identification number: 6014)

Response:

The current rule allows licensees to stipulate that HHS-certified laboratories use LOD for follow-up testing. Although testing at LOD for follow-up testing would be a good practice, the NRC declines to require LOD testing in this case. The NRC understands that MROs and EAP treatment personnel frequently encounter positive tests from the original detected use, especially during treatment, and that the procedure is to assure that there is a global decline in the concentration levels, understanding that some minor short term increases may not be indicative of new use.

11.1.8 Limit of Detection (LOD): Legal Challenges

Comment:

Three commenters objected to limit of detection testing because it could lead to results that would be unfair to those being tested which, in turn, would lead to increased legal challenges. Two commenters noted that there are acceptable reasons why some people's specimens may be out of specification. Testing those specimens at limit of detection could cause these people needless embarrassment. Another commenter stated that, because laboratories have differing limits of detection, using limit of detection will result in people unfairly being held to different standards. (Identification numbers: 7; 17; 25; 29; 6006)

Response:

The NRC believes that the technical foundation for limit of detection testing is sufficiently sound that no unfair test results will occur. Instead of causing more embarrassing circumstances, this rule revision reduces the embarrassment caused by the current requirement that individuals with dilute specimens provide their next specimen under observation. As stated in the May 1996 Federal Register notice, the NRC is well aware that not all questionable specimens are the result of subversion. The recommended testing procedures are intended to provide the MRO with enough information to limit the possibility of any wrong determination. Having specimens tested according to slightly different levels of detection at different laboratories will not lead to people being treated unfairly. There is already some variation in technical standards applying to several facets of the testing process, especially in different immunoassay techniques, different cut-off levels, and different specificity of the screening tests, in programs across the country.

11.1.9 Limit of Detection (LOD): Determination of Confirmed Positive Result

Comment:

Commenters asked for clarification as to whether test results for specimens of questionable validity that are positive at LOD are to be considered positive results. (Identification numbers: 5002; 6006)

Response:

The interpretation of such results would require MRO review and analysis. A positive test result at the HHS-certified laboratory's LOD is considered a laboratory confirmed positive test result. As with all such results, the MRO must review the result and determine if it was a confirmed positive test result. The MRO would need to evaluate the information. For example, the LOD positive could support other information that the donor was trying to subvert the testing process — a violation of the licensee's FFD policy. The MRO may consider a result which indicates the presence of a drug or drug metabolite at a lower concentration than the HHS-certified laboratory's LOD as one piece of information in assessing a questionable specimen.

11.1.10 Limit of Detection (LOD): For-Cause Testing

Comment:

One commenter suggested that the utilities could use guidance in the development of protocols to test at the limit of detection. And as noted in section 7.3.6 “For-cause Testing,” another commenter requested guidance about the circumstances under which it would be acceptable to test at LOD in for-cause testing situations. (Identification number: 6013)

Response:

NRC believes the rule provides sufficient guidance for licensees to develop their own protocols, which should be broad and flexible enough to use with a wide variety of situations, including for-cause testing.

11.2 Specimen Validity

Comments received on proposed revisions about specimen validity covered a wide range of issues. Several commenters opposed the new requirements for testing for specimen validity. Reasons for opposition included prohibitive costs and technical and procedural difficulties. Other commenters supported the new testing requirements and some offered suggestions regarding implementation procedures for specific tests such as creatinine testing. The application of CLIA was also a concern for some with regards to specimen validity testing. Other comments addressed the proposal to require procedures that identify masking attempts. Specific gravity testing was also discussed, with commenters addressing the timing of such testing and other specific testing and violation determination issues. Comments were also received regarding the cut-off levels required for suspect specimens.

11.2.1 Specimen Validity: Objections

Comment:

Several commenters recommended against the new requirements for testing for specimen validity. The commenters contended that such testing would be a very difficult, time consuming, and expensive and most HHS-certified laboratories are not equipped to do it. Also, current rule requirements are adequate for determining specimen validity. Some commenters proposed that, if the NRC decides that tests for specimen validity are necessary, the industry should develop guidelines for such testing. (Identification numbers: 7; 20; 25; 28)

Response:

The NRC disagrees with commenters contentions. Many laboratories currently conduct tests to determine specimen validity and do so as part of routine processing and as a normal cost of business. While the rule has always required some determination of specimen validity, the NRC believes that this requirement should be emphasized by inclusion of more explicit direction as to minimum standards for testing for specimen validity. Any extra effort that may be required in a few programs is more than justified by the reduction in potential subversion of the testing process. Because HHS has prepared guidance to recommend specific tests, such as creatinine, specific gravity, pH, and nitrites to determine specimen validity, the NRC does not anticipate a need for the development of industry guidelines.

11.2.2 Specimen Validity: Supporting Statements

Comment:

Six commenters made recommendations in favor of specimen validity testing. Four of these commenters specifically recommended that such testing should be conducted at HHS-certified laboratories. One commenter suggested that the acceptable creatinine testing limit should be less than 20 mg/dL, a normal pH result should be between 4.8 and 7.8, and an acceptable specific gravity result would be 1.003 or above. Another commenter recommended that specimens registering a specific gravity below 1.005 should be tested as a suspect specimen. Another commenter noted a seeming inconsistency between two rule revision proposals and recommended that section 2.7(e) be revised to read "...greater than or equal to 1.003...." (Identification numbers: 7; 10; 14; 29; 32; 36; 6011)

Response:

The NRC believes that licensees conducting on-site testing need to identify specimens of questionable validity so that all questionable specimens are tested at the HHS-certified laboratory and not prematurely disposed of by the licensee. It has been recognized for a long time that the best tests for determining specimen validity, in order of preference are: creatinine, SG, and pH. HHS and its Drug Testing Advisory Board have recently determined that, because of the wide variety of adulterants being used (in addition to numerous dilution techniques), a viable process for determining specimen validity should include these three tests, plus tests for nitrites. HHS has prepared guidance to recommend such testing by all HHS-certified laboratories. NRC's rule has been revised to adapt the HHS approach for use in NRC regulated programs. It requires tests for creatine, SG, pH, and nitrites for those specimens that are being tested on site and at the HHS lab. An edit has been made to eliminate the discrepancy noted by the commenter.

11.2.3 Specimen Validity: Creatinine Testing

Comment:

Two commenters recommended that creatinine testing be allowed but not required to be performed on site because of its complexity and expense. (Identification numbers: 7; 29)

Response:

See response 11.2.1

11.2.4 Specimen Validity: Immediate Recollection

Comment:

One commenter objected to requiring immediate collection of a second specimen from those employees who provide specimens with abnormal qualities because people can have dilute specimens for many reasons other than attempted subversion. (Identification number: 10)

Response:

The NRC recognizes that there are many reasons for dilute specimens other than an intention to subvert the testing process. The specimen validity process set forth in section 2.7(e) is intended to separate the questionable specimens from the valid specimens (which will be the vast majority of specimens being tested) and those that are clearly invalid. Since the MRO will be responsible for deciding what action, if any, is appropriate for those questionable specimens, section 2.7(e) requires special processing to provide the MRO with additional information. The NRC believes that the MRO will conclude that a questionable specimen containing trace amounts of drugs or metabolites is a violation of the licensee's FFD policy. As the rule is written, the MRO has the option of (i) obtaining information as to whether there is a legitimate explanation for a dilute specimen (the NRC believes this will occur most of the time) or (ii) collecting another specimen as soon as possible.

As noted above the NRC recognizes that there are many reasons for dilute specimens other than an intention to subvert the testing process. Reducing the need for collection of specimens under observation due to dilute specimens is one reason the NRC has decided to require that specimens of questionable validity be tested using special processing.

11.2.5 Specimen Validity: Tests for Adulterants

Comment:

Several commenters addressed the issue of whether or not the NRC should require tests that would determine the makeup of agents that have been added to specimens in an attempt to mask marijuana or other drugs. Four commenters were not in favor of the proposed requirement because such testing can be very difficult, time consuming, and costly. Instead, testing to identify adulterants or masking agents should be addressed by industry guidelines rather than a regulatory mandate. However, if adulteration is deemed to be sufficiently significant for regulation, some of these commenters recommended that a requirement to isolate adulterants should be imposed by HHS upon HHS-certified laboratories rather than being imposed upon licensees. Two commenters

recommended that testing for masking agents should be required. (Identification numbers: 7; 14; 20; 25; 32)

Response:

The NRC believes that determining specimen validity (including evaluation of nitrites) is sufficient and has decided to adapt the recommended guidance established by HHS for its certified laboratories to require tests for creatinine, SG, pH, and nitrites to determine specimen validity. Although useful information would be obtained if additional specific adulterants were identified, NRC sees no need to identify the adulterants to support sanctions taken by licensees.

11.2.6 Specimen Validity: Testing for Specific Gravity Prior to Screening

Comment:

One commenter noted that requiring testing for specific gravity to be done before screening would create several procedural challenges for HHS-certified laboratories. (Identification number: 18)

Response:

The intention of the requirement was that SG test results be considered prior to the determination of the outcome of the screening test result and that specimens not be destroyed until their validity has been determined and all tests completed. HHS has prepared guidance that establishes optional standards that can be followed in specimen validity tests in relation to screening test processes.

11.2.7 Specimen Validity: Testing for Specific Gravity at the Collection Site

Comment:

One commenter recommended that testing for specimen validity should be conducted at the time of collection whenever practical. Another commenter asked whether the NRC is proposing to require that a second specimen be collected as soon as possible when the validity of the first specimen cannot be determined. (Identification numbers: 36; 5002)

Response:

In order to eliminate as much as possible the potential for inaccurate determinations of specimen validity, the NRC has chosen to require that specimen validity testing be conducted in licensees' testing facilities, rather than at specimen collection sites, for those licensees that do on-site testing and at the HHS-certified laboratory for all specimens sent to the laboratory. The NRC will require the use of tests for creatinine, pH, and nitrites for specimens being tested on site; these can be accomplished using currently available HHS/FDA approved non-instrumented testing devices, such as "dip sticks." The NRC requires collection of a second specimen as soon as possible under the provisions of section 2.4(g)(15) if collection personnel suspect subversion, and section 2.4(f) when the validity of the specimen cannot be determined, which may be after the HHS-certified laboratory report is received.

11.2.8 Specimen Validity: Meaning of Terms

Comment:

Two commenters recommended that the NRC clearly define what is meant by “heavily adulterated or diluted” and when such specimens require testing for specimen validity. Another commenter asked for additional guidance as to whether or not questionable specimen validity due to low specific gravity includes low creatinine and below 20 creatinine levels. (Identification numbers: 36; 5002; 6014)

Response:

The terms “heavily adulterated or diluted” and “moderately diluted” were used in the May 1996 Federal Register notice (at 61 FR 21123) to help the public understand the recommended process and the expected conclusions. HHS has prepared guidance to recommend such testing by all HHS-certified laboratories. NRC's rule has been revised to adapt the HHS approach for use in NRC regulated programs. It requires tests for creatinine, SG, pH, and nitrites for those specimens that are being tested on site and at the HHS lab.

11.2.9 Specimen Validity: Is Low Specific Gravity a Violation?

Comment:

One commenter asked under what conditions a finding of low specific gravity should lead to a determination of FFD policy violation. In some cases there may be a reasonable and rational explanation for low specific gravity results. One commenter was concerned that employees may ask licensees to provide strong justification for findings of low specific gravity. (Identification numbers: 5002; 6006)

Response:

The NRC agrees that there are reasonable and rational reasons for low specific gravity. For this reason, low specific gravity does not constitute a FFD policy violation. It is instead a trigger for testing at the lowest concentration the laboratory can achieve, as part of the collection of information necessary to determine a specimen's validity. Specimens with a specific gravity outside of the prescribed range but within a range that is readily explainable would not be reported as a policy violation unless the specimen was found to contain proscribed drugs or drug metabolites at these lower testing levels or was determined to be a violation by the MRO for other reasons.

11.2.10 Specimen Validity: Testing at Half the HHS Cut-Off Level

Comment:

Two commenters disagreed with the proposal to test at one-half of the cut-off levels specified for each drug for suspect specimens (instead of the HHS-certified LOD level). One commenter recommended that limits of detection should be the standard. Another recommended that laboratory screening be at the licensee determined cut-off level. (Identification numbers: 7; 14)

Response:

The NRC concurs that the lowest levels of detection that can be achieved by each HHS-certified laboratory, rather than one half the cut-off levels specified for each drug, should be used to test suspect specimens.

11.2.11 Legal — Specimen Validity: CLIA

Comment:

Two commenters asked for clarification as to the application of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to the use of creatinine, specific gravity and pH testing to determine specimen validity. (Identification numbers: 6011; 6014)

Response:

In August of 1992, the Secretary of the Department of Health and Human Services exempted workplace drug testing from coverage under CLIA, pending a final decision to be made after further investigation. To date, the workplace moratorium is still in place. The Health Care Financing Administration is still investigating the application of CLIA to workplace drug testing and no final ruling has been made. The HHS Health Care Financing Administration Center for Laboratories has recently indicated that at this time CLIA is not applicable to the specimen validity testing procedures that were proposed in May 1996 (pH, specific gravity and creatinine testing); that would also apply to nitrite testing since all these tests are currently available on one "dip stick."

11.3 Temperature

Several commenters addressed the proposed narrower temperature range for acceptable specimens. The majority of commenters were against the requirement. Reasons included increased burden due to increases in recollection under direct observation and the desirability of maintaining consistency across Federal programs. A few commenters indicated support for the requirement because it would make subversion more difficult. Other comments received regarding temperature issues provided reasons for why a specimen may be outside the required range, suggested recommendations for alternative temperature ranges, offered suggestions for specific collection procedures, and sought guidance regarding imposing sanctions and other procedures.

11.3.1 Temperature: Factors Affecting Temperature

Comment:

Five commenters noted that the temperature of a specimen may be affected by several factors and that any of these factors may reduce the temperature below the proposed acceptable range. The factors cited were: specimen size, room temperature, specimen container temperature, time from urination to temperature measurement, and accuracy of temperature measuring device. Two commenters maintained that every attempt should be made to accurately measure the temperature of specimens smaller than 30 ml. If an accurate temperature is difficult to obtain and the sample size is less than 30 ml, it was suggested that the collector should note this in the remarks section of the chain-of-custody form. (Identification numbers: 10; 14; 25; 36; 6005)

Response:

The NRC, as mentioned in the May 1996 Federal Register notice at 61 FR 21121, recognizes that a number of factors including ambient temperature and sample size can affect the temperature of a specimen. Licensees are expected to take precautions to reduce the potential impact of these factors, such as providing a reasonable ambient temperature, measuring the temperature as soon as possible after collection, and using accurate temperature measuring devices. Specimens of less than 30 ml would require collection of additional specimens regardless of temperature. Each specimen should have its temperature measured and recorded with the understanding that smaller specimens may be cooler. The use of a peak thermometer would eliminate this issue for all specimens. See also the response to Summary Comment 11.3.2.

11.3.2 Temperature: Narrower Range

Comment:

A number of commenters discussed the proposed narrower temperature range for acceptable specimens. Several commenters opposed the proposed revision. One commenter pointed out that reducing the range to 94°F-100°F would burden licensees because they would have to recollect under direct observation many more specimens than if the range remained 90°F-100°F. One commenter suggested that 93°F rather than 94°F be the lower limit of the range, citing evidence that the number of specimens recollected in 1995 at his utility would have been reduced from 47 to 7 if 93°F were the lower limit of the temperature range. Other commenters also cited evidence for an increased number of recollections if the temperature band were reduced. However, two commenters agreed with the narrower range because it would make subversion more difficult.

Two commenters noted that since the existing rule allows the licensee to select a more stringent temperature range in order to minimize subversion, the existing temperature range of 90°F-100°F is adequate. One of the commenters suggested that the proposed narrower temperature range should be a goal rather than a program requirement. The commenter maintained that this would allow the rule to remain in concert with HHS and DOT regulations. Several other commenters also expressed the desirability of having consistency on this matter across Federal regulations. One commenter recommended that the HHS temperature band of 90°F-100°F be the standard. (Identification numbers: 7; 15; 20; 23; 25; 36; 6010; 6011; 6019; 6020)

Response:

Upon reconsideration, the Commission has decided not to adopt a narrower temperature range. Insufficient data exists showing whether there would be a significant number of true positives identified using the more restricted temperature range that are currently classified as negatives. Thus, it is unclear whether the benefits of identifying these true positives outweighs the cost of additional confirmatory testing for eliminating false positives.

The NRC concurs with the commenters' desire to have consistency across Federal programs and, when practicable, has endeavored to achieve this consistency. However, as discussed above (Summary Comments 4.2.1 and 4.2.2) the NRC has concluded that some program differences are necessary.

11.3.3 Temperature: Sanctions for Specimens with Unacceptable Temperature

Comment:

One commenter asked whether or not a sanction would be imposed on an individual who provides a specimen measuring one degree colder than the acceptable lower limit of 94 °F when the collection site was excessively cold. The commenter inquired whether or not there would be room for interpretation based on the coldness of the collection room. (Identification number: 5002)

Response:

The Commission has decided not to adopt a narrower temperature range. See discussion under 11.3.2.

11.3.4 Temperature: Oral Temperature

Comment:

One commenter observed that the proposed section 2.4(f)(2) does not address any case in which the donor's oral temperature is normal (37°C/98.6°F), but the temperature of his or her specimen is less than the acceptable lower limit of 34°C/94°F. The commenter suggested that the proposed wording be amended to state that if the temperature of the specimen is less than the acceptable lower limit and the individual fails to provide an oral body temperature, or his or her oral body temperature varies by more than 1°C/1.8°F from the temperature of the specimen, then there is reason to believe that the specimen might be altered or substituted. (Identification number: 36)

Response:

Section 2.4(f)(2) has been revised as recommended by this commenter, and consistent with the DOT regulation.

11.3.5 Temperature: Wording of Section

Comment:

One commenter discussed the grounds constituting a reason to believe that an individual may alter or substitute a urine specimen. The commenter maintained that section 2.4(f) conflicts with section 2.4(f)(1) because section 2.4(f) states that an individual may only alter or substitute a urine specimen "to be provided." (Identification number: 36)

Response:

The NRC has reviewed this section's language and determined that it is not in conflict and is sufficiently clear. Individuals who previously submitted a specimen that was found to be questionable will provide subsequent specimens under observation. This would apply if the subsequent collection was a recollection under section 2.4(g)(15)(ii), if the validity of a specimen cannot be determined under section 2.7(e), and all future testing of the individual under section 26.24(a).

11.4 Other Subversion Issues

Other subversion issues were also discussed by commenters, such as the role of deterrence within the program, the increased need for information on subversion techniques, specific rule revisions that appear to single out FFD personnel, notification time in the testing process, definition clarification, difficulties with for-cause testing after suspicion of subversion, etc.

11.4.1 Other Subversion Issues: Tests for Dilution and Detection of Masking Agents

Comment:

In response to the NRC's request for comment regarding the inclusion of the new section which permits tests to detect evidence or dilution and the detection of masking agents, one commenter stated, in support of the measures to detect attempts of subversion, that "the deterrent effect is what the program is all about. If people can adulterate without detection then the integrity of the entire program is in question." Another commenter agreed that deterrence is the major purpose of the program, but disagreed that anti-subversion measures support deterrence. This commenter also suggested that the attention being paid to subversion by the NRC is unnecessary and constitutes an unjustified burden on licensees. (Identification numbers: 6; 7)

Response:

The NRC appreciates the responses to its request for comments on this matter. The NRC has determined that subversion has the potential to undermine the effectiveness of the FFD program to deter and detect illicit drug and alcohol use and that anti-subversion measures are eminently justified in the interest of protecting public health and safety. The anti-subversion measures have both detection and deterrence goals.

11.4.2 Other Subversion Issues: Updates on Subversion Techniques

Comment:

One commenter suggested that the NRC should provide licensees with technical updates regarding current subversion techniques so that the licensees can improve the performance of their current programs. (Identification number: 7)

Response:

An update on subversion is provided in Chapter 6 of NUREG/CR-6470 *Fitness for Duty in the Nuclear Industry: Update of the Technical Issues 1996*, in support of the NRC's FFD rulemaking effort. In addition, licensee reported cases of subversion have been included in the Lessons Learned reported by licensees in the Annual Summary of Program Performance Reports (NUREG/CR-5758) in Appendix C. Future Annual Program Performance Reports which will summarize data on subversion attempts by type [section 26.71(d) reports] should also be useful. The NRC also hopes that licensees will continue to provide summaries of newly identified subversion techniques and will ensure they are reported in future annual reports.

11.4.3 Other Subversion Issues: Consistency Across Programs

Comment:

Commenters noted their support for the NRC's changes and enhancements to reduce the potential for subversion and suggested that these kinds of guidelines should be uniform across various agencies. An example of the difficulties in the consistency of current guidance from different agencies was provided. (Identification numbers: 8; 5003)

Response:

The NRC appreciates the comment and will share it with other Federal agencies.

11.4.4 Other Subversion Issues: On-Site Non-Instrumental Testing Devices

Comment:

Two commenters addressed the susceptibility to subversion of on-site non-instrumented testing devices. (Identification numbers: 7; 9)

Response:

See sections 3.8 and 9.1.1 "Use of Non-instrumented Testing Devices" for the response to these and other related comments.

11.4.5 Other Subversion Issues: Trustworthiness of FFD Personnel

Comment:

Two commenters suggested that there is no evidence that FFD personnel are less trustworthy than others and maintain that more extensive requirements for background investigations of FFD personnel are not necessary. Hence, the requirement should be eliminated rather than just reduced from 3 to 5 years. Another commenter agreed with the proposed reduction from 3 to 5 years. (Identification numbers: 10; 20; 23)

Response:

The continuing requirement that FFD program personnel be subject to background checks and psychological evaluations does not indicate that these personnel are any less trustworthy than others. Instead, it is meant to ensure that only people having the highest standards for honesty and integrity will be employed in these positions that are of such central importance to the integrity of the FFD program.

11.4.6 Other Subversion Issues: Is Dilution Evidence of Subversion?

Comment:

Two commenters noted that it is difficult to assess whether a dilute specimen is the result of an intentional effort aimed at subverting the testing process. One of these commenters noted that there is no way of proving an intentional dilution and that efforts to overcome a "shy bladder" are likely to result in a dilute specimen. (Identification numbers: 18; 5002)

Response:

The NRC agrees that it is not possible to determine the basis for a dilute specimen (unless the specimen is outside the range possible for any urine specimen). For this reason the NRC is requiring that such specimens be tested under the process described in section 2.7(e). When the validity of the specimen cannot be determined, another specimen is collected as soon as possible. In addition, if after reviewing the results of the processing described in section 2.7(e) the MRO determines that there is no reason to believe there was an attempt to subvert the testing process, an observed collection is not required at subsequent testing occasions. Also see Summary Comment 13.1.2.

11.4.7 Other Subversion Issues: Period Between Notification and Specimen Collection

Comment:

Several commenters responded to changes regarding limiting the amount of time from notification to specimen collection. One commenter noted that a review of comparative drug screening records across several plants revealed that plants with unlimited time periods for reporting had a significantly higher number of “near positives” than those that had limitations on time for reporting. This commenter strongly supported the change, and suggested that less than an hour would be an appropriate time. Another commenter agreed and suggested that the key to preventing subversion is the observation of the individual during the interval between notification and testing. Conversely, another commenter suggested that a shorter notification time will not prevent subversion or dilution of specimens and cited cases in which dilution occurred after a 15-minute notification period. (Identification numbers: 18; 20; 29; 5003)

Response:

The NRC believes that limiting the amount of time from notification and testing is an important step in preventing subversion. While, as one commenter noted, dilution or adulteration can still occur when this time period is short, a shorter period between notification and testing provides less opportunity for such subversion attempts.

11.4.8 Other Subversion Issues: Definitions of Terms

Comment:

Two commenters requested specific definitions for terms relevant to rule revisions regarding subversion. One commenter provided a number of specific suggestions regarding the definitions of “reason to believe” that an individual may provide a suspect specimen. Another commenter wondered what constitutes “in vivo” dilution. (Identification numbers: 36; 5002)

Response:

As discussed in NUREG 1385, the NRC believes that “reason to believe” is clear in its meaning and does not require a definition. A discussion of “in vivo” dilution is provided in section 2.7(e) and NUREG/CRs 5227, Sup. 1 and 6474, Chapter 6. “In vivo” dilution refers to dilution of the specimen in the body (e.g., drinking large quantities of liquid) as compared to “in vitro” dilution, which is dilution outside the body (e.g., adding water to the collection cup).

11.4.9 Other Subversion Issues: Testing for Adulteration and Dilution

Comment:

A number of commenters responded to the NRC's request for comments regarding requirements for testing for adulteration and dilution. One commenter suggested that dilution testing (pH and creatinine) be required and adulteration testing (for masking agents) be permitted as requested by collection personnel, laboratory personnel, or the MRO. Another commenter suggested that the rule should not address these types of testing, and that, instead, industry guidance should be provided. This commenter, referencing NUREG/CR 6470, provided specifics of what might be included in such guidance. Another commenter suggested that the rule should stipulate that the licensee's laboratory is to report an "abnormal response" and that the specific adulterant need not be identified. Another commenter would prefer that testing of this type be at the discretion of the licensee and not required because the use of these substances is not pervasive and the costs of such testing are not justified (the commenter presented no evidence that the use of these agents is not pervasive). Another commenter requested information regarding recent research on adulterants. Finally, one commenter reported on experience with using specific gravity testing on site, noted the difficulties with using creatinine on site (e.g., CLIA), and also noted that there are reports of new advertisements for adulterants that contain creatinine that would overcome the usefulness of the creatinine test. (Identification numbers: 6; 7; 10; 23; 5002; 6011)

Response:

It has been recognized for a long time that the best tests for determining specimen validity, in order of preference are: creatinine, SG, and pH. HHS and its Drug Testing Advisory Board have recently determined that, because of the wide variety of adulterants being used (in addition to numerous dilution techniques), a viable process for determining specimen validity should include these three tests, plus tests for nitrites. HHS has prepared guidance to recommend such testing by all HHS-certified laboratories. NRC's rule has been revised to adapt the HHS approach for use in NRC regulated programs. It requires tests for creatine, SG, pH, and nitrites for those specimens that are being tested on site and at the HHS lab. An edit has been made to eliminate the discrepancy noted by the commenter. Some information on adulterants is provided in Chapter 6 of NUREG/CR-6470. It should also be noted that CLIA requirements do not apply to on-site specimen validity testing.

11.4.10 Other Subversion Issues: For-Cause Testing After Subversion Attempts

Comment:

One commenter noted that there are problems with the requirements for for-cause testing after suspicion of subversion. The commenter expressed concern that a for-cause test which is negative may outweigh the earlier evidence of subversion. This commenter recommended deleting the requirement for a for-cause test in cases of attempted subversion. (Identification number: 36)

Response:

The NRC agrees that for-cause testing in cases of suspected subversion should be based upon the judgment of the licensee as to the value of such testing and should not be specifically required in the rule. It has revised section 26.24(a)(3) accordingly.

12.0 Violation Determination and Sanctions

Commenters raised an assorted group of issues and suggestions regarding FFD violation determination and sanctions. For example, several commenters requested guidance regarding the sanctions that should be imposed for specific violations (e.g., abuse of over-the-counter drugs, low specific gravity, laboratory confirmed positive tests, etc.). Clarification was also requested and recommendations suggested regarding the meaning of work status during suspension periods. Other comments were received requesting clarification of specific instances that may constitute violations. In addition, commenters questioned the NRC's role in establishing methods of compliance and some raised objections to the proposed sanctions to alcohol and prescription drug violations. Commenters also addressed responses to other causes of impairment covered by the rule, in addition to illegal substances, such as impairment from legal drugs, psychological impairment, and impairment from fatigue.

12.1 Violations

The commenters objected to and suggested alternatives to certain policies regarding violation determination and reinstatement of the individual including the specification of who determines fitness to return to duty and the requirement to remove individuals from duty based on on-site screening positive results.

12.1.1 Violation Determination: Removing Individuals Prior to MRO Review

Comment:

Two commenters suggested that individuals with laboratory confirmed positive test results be removed from duty until they are interviewed by the MRO. This would prevent the individual from entering the protected area until a determination is made by the MRO. The commenters make the point that this policy is a lot less questionable than removing individuals from duty based on on-site screening positive results for THC or cocaine, as currently allowed under section 26.24(d)(2). In addition, it was noted that since MROs often have difficulties in contacting individuals to come in for consultation, this could be an important safety measure. (Identification numbers: 10; 6005)

Response:

The NRC believes that permitting automatic suspension of access based solely on a laboratory confirmed positive test would be an unnecessary abridgement of individual rights, and would achieve little enhancement of safety. The NRC also believes that the MRO and the licensee have sufficient flexibility under the original rule to address safety concerns in situations in which people who have laboratory confirmed positive test results have failed to contact the MRO after being requested to do so. In response to commenters' concern about situations in which the MRO cannot interview individuals who have had laboratory confirmed positive test results, the NRC has revised § 2.9(c) of Appendix A. These revisions provide guidance regarding the disposition and reporting of results when a worker leaves the employ of the licensee or for other reasons cannot be interviewed by the MRO after a laboratory confirmed positive test result. Provisions are also included for subsequently correcting the employment records when appropriate.

12.1.2 Violation Determination: Removal After Presumptive Positives

Comment:

One commenter opposed the removal from duty of individuals based on non-confirmatory positive test results of any substance. (Identification number: 17)

Response:

The NRC continues to believe that the provisions of section 26.24(d)(2) providing for removal from duty based on presumptive positive screening test results for cocaine or THC contain adequate protections of individual rights and are in the interest of assuring public health and safety.

12.1.3 Violation Determination: Fitness Determinations

Comment:

One commenter objected to the NRC's specifications that personnel who have been denied unescorted access for being impaired and in violation of the licensee's fitness-for-duty policy must be determined fit to perform activities by an appropriate manager and licensed physician before being allowed to return to duty. The commenter maintained that the NRC's role should be to set standards, not to determine how the licensee should comply. (Identification number: 7)

Response:

Because there have been several instances in which licensees had "automatically" returned workers to duty without a determination of fitness, the NRC believes its expectations need to be clarified. The NRC believes that an adequate determination of fitness is necessary to protect public health and safety and is therefore a key element in the FFD program. The NRC is setting the standard to be used by licensees in section 26.27(b)(1) that no individual determined to be impaired, whose fitness may be questionable, or in violation of a licensee FFD policy shall return to duty until determined to be fit for duty by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. However, in those instances where an individual tests negative in a for-cause test, only an appropriate manager need make a determination of fitness. The Commission has decided not to adopt the requirement that a medical determination of fitness be performed to evaluate employees who test negative in a for-cause test. In situations such as preaccess and return-to-duty testing, the fitness determination is ordinarily made during normal work hours when the MRO is on-duty. By contrast, the need for a medical determination after a negative for-cause test could occur during off-normal work hours when the MRO is not available. In this situation, the licensee would have the following options: (1) provide an MRO on a 24-hour or as-needed basis or (2) defer the medical determination until normal work hours. The added costs and reduced flexibility would only occur in negative for-cause tests, and there is insufficient data to show that such costs would be justified in terms of the identification of significant numbers of unfit workers would only be identified as unfit by the MRO. Therefore, the Commission has decided that a medical determination after a negative for-cause test is not warranted.

12.2 Sanctions

Several issues regarding sanctions were discussed by the commenters including requests for clarification on sanctions that apply to FFD personnel and individuals who are suspended under Part 26, objections to the sanctions being the same for alcohol and prescription/over-the-counter drugs as for illegal drugs, sanctions that are based on back calculation for BAC, and questions about sanctions for abuse of over-the-counter drugs, specimens with low temperature or specific gravity, and positive results at LOD.

12.2.1 Sanctions: FFD Personnel

Comment:

One commenter requested clarification as to what sanctions would be imposed for FFD personnel who test positive. (Identification number: 1)

Response:

The NRC believes that any act that would cast doubt on the honesty and integrity of FFD program personnel should result in removal from the FFD program responsibilities listed in § 26.2. The § 26.27(b)(3) requirement that employees who are suspended, but still in a work status during their suspension period, remain covered by the FFD program with respect to applicable behavioral observation, chemical testing, and sanctions for violations of FFD policy has been revised to clarify that only people who are still in the employ of the licensee need be covered.

12.2.2 Sanctions: Coverage During Suspension

Comment:

Three commenters requested clarification regarding the proposed requirement that individuals suspended from activities covered by this part, but still in a work status during their suspension period, remain covered by the FFD program with respect to applicable behavioral observation, chemical testing, and sanctions for violations of FFD policy. All three commenters recommended that this requirement be reworded for clarification of the phrase "in a work status."

One commenter recommended that only those individuals who continue in work status with the licensee after being removed under Part 26 should be subject to behavioral observation, chemical testing, and sanctions during the period that they are removed from duty. The commenter was concerned with the implications for continuing these activities for contractors who would no longer have work status but would some how be required to still be covered by a program. (Identification numbers: 7; 21; 36)

Response:

Section 26.27(b)(3) has been revised to clarify that only individuals still in the employ of the licensee pending reinstatement of unescorted access need be covered by chemical testing and sanctions and that only those in a work status must also be covered by behavioral observation.

12.2.3 Sanctions: Sanctions for Alcohol

Comment:

Several commenters objected to making the sanctions for alcohol and prescription or over-the-counter drug violations the same as those for illegal drugs. Commenters cited as rationales the differences in legality of use, the need for re-education rather than sanctions for alcohol abuse, the more obvious and immediate impairment caused by alcohol abuse, and the fact that HHS and DOT do not dictate sanctions for first violations of alcohol or legal drugs. One commenter agreed with the NRC's logic regarding the importance of alcohol sanctions in a fitness-for-duty program, but argued that from an employer policy perspective, there are strong incentives for maintaining a distinction between illegal drugs and alcohol. (Identification numbers: 7; 10; 15; 17; 28; 5003)

Response:

It has always been the Commission's intention that licensees have sanctions for alcohol abuse that would adequately deter such abuse. In the Commission's view, the sanctions that some licensees have adopted do not provide sufficient deterrence. As discussed in Chapters 3 and 7 of NUREG/CR-6470, alcohol represents one of the most serious problems in workplace impairment and problems with alcohol abuse by workers are as difficult to address and resolve as those created by illegal drug abuse. Therefore, the rule has been revised to make clear that alcohol abuse presents as significant a threat to safety as does drug abuse and that licensee policy regarding sanctions must respond to this adequately. (See Item 10.3.3 for further comment on this change.) Sanctions for abuse of prescription and over-the-counter drugs must be adequate to deter such abuse, but specific minimum sanctions are not prescribed by the NRC at this time. See also Summary Comment 10.3.3.

12.2.4 Sanctions: Back Calculation of BAC

Comment:

One commenter requested guidance regarding what sanctions could or would be imposed based on back calculation for alcohol BAC. (Identification number: 5002)

Response:

The NRC has amended the rule to remove the proposed requirement for back calculation, or extrapolation by the MRO. Instead, having a BAC of 0.03 percent or greater after one hour on duty or 0.02 percent or greater after two hours on duty will be a FFD policy violation and the same sanctions that apply to 0.04 percent BAC would apply.

12.2.5 Sanctions: Sanctions for OTC Drugs, Low Temperature, Low Specific Gravity

Comment:

One commenter asked what sanctions the NRC would require (or suggest) for abuse of over-the-counter drugs, a specimen with low temperature, or a specimen with low specific gravity. Two commenters raised a question regarding whether a result that was positive at LOD was a "positive" and would result in a sanction. (Identification numbers: 18; 5002; 6006)

Response:

The NRC does not specify sanctions for abuse of over-the-counter drugs except that the licensee policy must include sanctions that effectively deter such abuse. Licensees should rely on MRO judgment regarding the nature and magnitude of such abuse and appropriate response.

Specimens with a low specific gravity or low temperature do not by themselves represent policy violations; additional information, such as the donor's fluid intake and core body temperature, should be obtain. All such information, including information obtained from specimen validity and LOD testing must be evaluated by the MRO to determine if there is a violation of the licensee's FFD policy. A specimen of questionable validity that shows evidence of dilution must be tested at the HHS-certified laboratory's LOD as required by section 2.7(e)(4) of Appendix A. If the test indicates the presence of illegal drugs or metabolites, the MRO should determine that the donor used drugs in violation of the licensee's FFD policy, and may determine that the donor attempted to subvert the testing process. The sanctions set forth in §26.27(b) and (c) apply, depending upon whether subversion was involved. If, however, the LOD testing produces a negative result, the MRO can exercise discretion by determining that it is a true negative or by determining that there is still a question and more information (potentially including an observed recollection) is required.

12.3 Responses to Impairment for Reasons Other than Illegal Drugs and Alcohol

Commenters requested additional guidance as to how to deal with access issues for workers whose fitness for duty is impaired for reasons other than drug or alcohol use.

12.3.1 Spousal Use of Prescription Drugs

Comment:

One commenter agreed with the NRC's policy of permitting the MRO to use prudent judgment in dealing with sensitive issues such as spousal use of prescription drugs. This commenter strongly supported the formal articulation by the NRC of its approach to spousal use of prescription drugs, noting that MRO judgment should be relied upon in these cases. (Identification numbers: 8; 5003)

Response:

The NRC concurs that it is prudent to rely on MRO judgment in these cases and notes that prudent actions should in all cases be taken to assure that there is no substance abuse or fitness problem that may jeopardize public health and safety.

12.3.2 Psychological Impairment

Comment:

One commenter requested that the NRC provide specific guidance on when licensees should deny unescorted access in cases where workers appear not to be fit for duty for psychological as opposed to substance abuse reasons. (Identification number: 6011)

Response:

General guidance regarding workers who appear unfit for duty for any reason is provided under the general performance objectives (sections 26.10(a) and (b)). In addition, section 26.27(b)(1) requires that personnel whose fitness may be questionable be removed until determined to be fit. That may be the result of any condition noted in section 26.24(a)(3), displays of aberrant behavior, violence, etc. that would cause doubt as to whether the worker's responsibilities would be met safely and competently. Licensee FFD programs should be designed to address all situations that may cause workers to be unfit for duty. Regardless of the cause of the fitness problem, appropriate action should be taken to assure that an individual does not work with any condition that would jeopardize the health or safety of him or herself, other plant personnel, or the general public.

12.3.3 Fatigue or Other Impairment

Comment:

One commenter requested guidance with regard to allowing employees on site with escorted access when they are not fit for duty either because of fatigue, alcohol, or for other reasons. (Identification number: 5002)

Response:

The provision in the rule that permits escorted access when a person is not fit was primarily intended to prevent a licensee from being automatically in violation if the licensee determines that the person is unfit while at work; it also permits a licensee to utilize an individual who may otherwise be unfit. This means that the licensee is aware of the individual's condition, and has determined that its needs must be met by using this individual, and the licensee can accommodate the situation to ensure there is no safety hazard to the worker, other workers, and the public. Licensees are expected to use prudent judgment in allowing employees with a condition that makes their fitness for duty questionable to perform work under escort. The NRC recognizes that an employees' specific skills and/or expertise may make such an accommodation desirable.

13.0 Protecting Workers Rights and Appeals

Several questions were raised by commenters regarding the protection of workers rights and appeal policies. Issues of concern included various appeal procedures, such as when workers should have the right to appeal and the effect of a lack of a split specimen on the appeals process. Comments were also made on workers' rights regarding split specimens, unescorted access authorization pending for-cause test results, privacy issues, and access to records.

13.1 Protecting Worker's Rights

Commenters recommended what information should be available to employees regarding FFD policy violations and what information should not be available to employers; expressed concern regarding specimen collection under direct observation and a statement about early laboratory quality; and requested clarification on ownership of the split specimen, removing employees from unescorted access pending for-cause test results, handling worker confidentiality when establishing a prior history of abuse, and record retention.

13.1.1 Protecting Workers Rights: Making Information Available

Comment:

Two commenters recommended that the information pertaining to the determination of FFD policy violations be made available to employees should be limited to test results and summary information regarding the violation determination. (Identification numbers: 7; 10)

Response:

The NRC believes that employers should provide copies of all relevant records related to the determination of a FFD policy violation, upon request, to the employee affected. The NRC is aware that, contrary to its intent, some licensees have made it difficult to obtain these records. Employees need such records to have a fair and complete opportunity to appeal FFD policy violations. The NRC has, therefore, retained this revision to section 26.29 to reiterate that persons covered by the rule must have full and convenient access to documents pertaining to employment actions taken in response to Part 26 requirements.

13.1.2 Protecting Workers Rights: Observed Collection After a Dilute Specimen

Comment:

One commenter expressed misgiving about allowing direct observation specimen collection after the person being tested has submitted a first specimen deemed to be dilute. The commenter pointed out that dilute specimens can be caused by a number of common and innocent conditions. (Identification number: 18)

Response:

The NRC agrees that it is not possible to determine the basis for a dilute specimen (unless the specimen is outside the range possible for any urine specimen). For this reason the NRC is requiring that such specimens be tested under the process described in section 2.7(e). In addition, if after reviewing the results of the processing described in section 2.7(e) the MRO

determines that there was no violation of the licensee's FFD policy, an observed collection is not required on subsequent occasions. When the validity of a specimen cannot be determined, another specimen is collected as soon as possible under observation. Also see Summary Comment 11.4.6.

13.1.3 Protecting Workers Rights: Records of Self Referrals to EAPs

Comment:

One commenter recommended against the policy that allows records pertaining to employees' self referral to EAPs to be made available to their employers. (Identification number: 23)

Response:

The NRC agrees that records regarding self referrals to EAPs should not be available to employers. Self referrals should result in a notification of the employer, as required by section 26.25, only if the EAP counselor determines, based on information obtained from the self referral, that the individual constitutes a threat to the health and safety of himself or herself or to others.

13.1.4 Protecting Workers Rights: Use of HHS Laboratories Prior to 1990

Comment:

One commenter strongly disagreed with the NRC's statement that many of the laboratories certified by the end of 1989 did not meet current performance standards for accuracy and reliability, that confirmation tests may not have been conducted in some cases, and that test results may not have been reviewed by technically qualified people in all cases. The commenter stated that the National Laboratory Certification Program has always prevented such occurrences. (Identification number: 25)

Response:

The intention of the statement was to emphasize that prior to the required implementation date of the FFD rule (January 3, 1990), nuclear power plant FFD programs, which were in place for many years, were not required to use certified laboratories. Hence, test results obtained before January 3, 1990 may not have been based on GC/MS testing, or may have been tested by an uncertified laboratory. These results may also not have had MRO review. The NRC regrets any implication that the HHS laboratory certification program has not been adequate since its inception in 1988.

13.1.5 Protecting Workers Rights: Split Specimens

Comment:

One commenter asked whether split specimens are to be considered the property of the employee and, if so, whether MROs can order these split specimens to be tested. (Identification number: 5002)

Response:

MROs must process the split specimen for testing only when requested by the specimen donor. The split specimen cannot be tested without the donor's request.

13.1.6 Protecting Workers Rights: Removing Employees Pending Resolution of Test Results

Comment:

One commenter asked whether the NRC expects licensees to remove employees from unescorted access pending for-cause test results and how this should be managed in a way that would balance the need to take action with protecting worker rights. (Identification number: 6011)

Response:

If there is any reason to question the individual's fitness, he or she should be removed and not permitted to return to unescorted access status until the fitness-for-duty issue is satisfactorily resolved and the individual determined to be fit. Individuals may be returned to duty pending drug test results based on a negative alcohol test result and a medical and management determination of fitness. Where restoration of access is pending a determination of fitness, the licensee should be discreet. Co-workers will know the person is absent from work, but the licensee should not make public the reason for the absence.

13.1.7 Protecting Workers Rights: Confidentiality and Privacy

Comment:

One commenter requested clarification as to how licensees should handle worker confidentiality and privacy issues when establishing a prior history of substance abuse. Would prior history of abuse include the fact that the employee has self referred to an EAP for substance abuse or that the employee has had a prior positive drug test in a Department of Transportation-mandated substance abuse program? (Identification number: 6011)

Response:

For the most part, in self referral cases, the information provided by the individual would be regarded as medical treatment information and not disclosed under suitable inquiries (see NUREG 1354). The fundamental philosophy of the EAP is to encourage self referrals. So, unless the individual is a threat to himself, herself, or others (including threats to public safety resulting from his or her work at a nuclear power plant) the information should be confidential and need not be included in the individual's history of substance abuse. An individual with a positive test result in a DOT program or any other public or private testing program would have a history of substance abuse. See Summary Comment 6.5.3 for related comments.

13.1.8 Protecting Workers Rights: Use of Unconfirmed Positive Results

Comment:

One commenter requested clarification regarding a portion of section 26.24(d)(2), which states, "the tested individual must be provided a statement that the records ... have not been retained...".

The commenter maintained that there are instances in which historical data on unconfirmed positives is used to assist in decisions on current cases. (Identification number: 5002)

Response:

Section 26.24(d)(2)(iv) requires that if the licensee has temporarily removed a worker based upon a on-site presumptive positive screening test result, and a negative test report is received from the HHS-certified laboratory, or the results are not confirmed by the MRO, all records of the temporary removal must be purged, and no disclosure made in response to a suitable inquiry. As a further safeguard, the tested individual must be provided a statement that the records of the temporary removal have not been retained. Although not stated in the rule, the NRC expects that any personal recollections of such personal removals must not be considered.

The requirement of 26.24(d)(2) to purge records after the basis for temporary removal has been invalidated has no relationship to the retention of laboratory reports or other information related to the collection and testing of specimens by licensees for program administration purposes.

The NRC desires to respond to the commenter's implied question, "What records can be retained and used for current decisions?" as follows:

A decision by an MRO must be based on all relevant information the MRO obtains with respect to the test results being reviewed. That is, a previous positive test result (or policy violation) must not influence an MRO's current decision as to whether a current specimen is positive or there is some other FFD policy violation, such as attempted subversion. However, the history of substance abuse, without regard to the interval between violations, must be included in the imposition of the current sanctions, as required by § 26.27. Revisions to 26.71 have been made to make it clear that records pertaining to a determination of a violation of FFD policy must be retained at least 5 years, whereas records pertaining to revocation of authorization to perform activities within the scope of Part 26 must be retained for the duration of the license.

Relevant information that may be considered during an unusual situation may include information not normally considered during an MRO's review. In many of the unusual cases which are known to the NRC, MROs have had to take more active roles in the testing process by trying to determine what information is needed and how it should be evaluated. For example, abuse of over-the-counter (OTC) medications used to treat symptoms of colds and allergies frequently contain synthetic methamphetamine, which can cause anxiety, nervousness, and loss of sleep. The synthetic methamphetamine may be abused as a substitute for methamphetamine, a highly addictive stimulant that can cause paranoid and violent behavior and which is replacing cocaine as a drug of choice by many substance abusers. The use of pseudoephedrine tablets for reduction to a concentrated methamphetamine is growing in popularity and frequency. Large concentrations of this OTC medication in urine can result in a presumptive positive screening test for amphetamine that will fail to confirm with GC/MS. Rather than declaring the results negative, the MRO needs to obtain more information and determine if there is a fitness issue that could jeopardize safety. The MRO should request GC/MS tests for the specific compound of interest. The MRO can then evaluate the observed behavior, the presumptive positive screening test results, the special GC/MS testing, and any information provided by the worker. Once the MRO has determined that a violation of policy has occurred and the screening test results are relevant to that determination, the restrictions of § 26.24(d)(1) concerning access to these test results no longer apply.

13.2 Appeals

Commenters recommended changes to the proposed rule revisions that would impact who would have the right to appeal FFD policy violations and under what conditions. Commenters also noted issues, requested clarification, and made recommendations regarding the analysis of split specimens and the reanalysis of primary specimens.

13.2.1 Appeals: Scope of Appeal Right

Comment:

Three commenters recommended changes to proposed rule revisions that would affect employees' right to appeal FFD policy violations. One commenter suggested that the extension of the right of appeal to applicants be extended to only those who have been given provisional employment subject to meeting unescorted access requirements. Another commenter recommended that applicants for unescorted access be granted the right to appeal such violations only when their employment would be adversely affected by denial of unescorted access. This commenter also recommended that the rule make clear that, since the splitting of specimens is done at the option of licensees, the lack of a split specimen should not affect the outcome of appeals when retests of primary specimens are positive. Another commenter asked whether the NRC is proposing to require that an appeal must be conducted by more than one person. The last commenter asked whether the fact that it is difficult to clearly determine whether a person has deliberately hydrated him or herself could adversely affect the appeals process. (Identification numbers: 7; 20; 5002)

Response:

When the Federal government requires a program that could jeopardize any person's career, proper safeguards such as the right to an effective appeal must be required to ensure that decisions affecting careers are based upon accurate information. Therefore, the NRC has always intended and continues to require that all persons, including applicants for unescorted access, who are tested under Part 26 have the right to appeal FFD policy violation determinations. Also, as long as a person has been subjected to a test, that person should have the right to appeal determinations based on that test result regardless of whether he or she has been given a provisional offer of employment. This right cannot be dependent upon a finding that a denial of unescorted access would adversely affect a person's future employment. Licensees cannot be expected to know all the future employment consequences of a policy violation when determining whether or not an applicant should be granted an appeal. Insofar as whether the lack of a split specimen should affect the outcome of an appeal is concerned, the NRC notes that split specimens are not required by Part 26, but may be required under the licensee's program. Whether or not lack of a split specimen should be considered in specific employment actions should be left up to the adjudicators of those actions.

In response to the question about the number of people required to conduct an appeal, the NRC believes that the need for those conducting appeals to be independent and objective must be emphasized and strengthened. To accomplish this, the use of the word "persons" in section 26.28 is intended to indicate that each appeal is to be conducted by more than one person. As the rule has always required, persons conducting appeals must be impartial members of the licensee's staff who are independent of the FFD program administration. The fact that it is difficult to clearly determine whether a person has deliberately hydrated him or herself should not adversely affect the appeals process. When there is an indication of possible hydration, the evidence of such

hydration, to the extent it exists, must be weighed and considered along with all other information that led to the determination of FFD policy violation.

13.2.2 Appeals: Payment for Specimen Analysis

Comment:

Six commenters submitted comments regarding payment for the reanalysis of “primary” specimens and the analysis of “split” specimens when employees pursue appeals. Several commenters recommended that employees who request specimens be tested for purposes of appeal be required to pay the cost of those tests. Their reasons included increased costs for licensees and predictions that employees will ask for split specimens to be tested for purposes of appeal after all confirmed positive test results. Another commenter questioned if using a second laboratory to test split specimens will require an audit of that laboratory. The commenter also wanted to know if the licensee could direct the worker requesting the specimen re-analysis to use the licensee’s back-up lab. (Identification numbers: 21; 30; 35; 36; 5003; 6014)

Response:

The NRC continues to believe that it is better if employees who are pursuing appeals are not required to pay for reanalysis of their specimens or analysis of their split specimens. However, requiring reimbursement to the licensee of these costs, should these subsequent tests also be positive, is an acceptable measure to control unwarranted appeals. In the case of split specimens, the worker essentially “owns” the specimen and can have it analyzed at the laboratory of his or her choice. Practically speaking, the NRC understands that the laboratories are reluctant to test individual specimens and desire some sort of contractual agreement which, in effect, would limit the individual's choice of a laboratory for analyzing a split specimen. The licensee is free from responsibility of auditing the laboratory, however, the licensee may have some concerns that the laboratory chosen by the worker does not have equivalent technical capabilities to those of the laboratory with which the licensee has a contract (e.g., it may have a higher LOD). Licensees could assure the use of a laboratory with equivalent technical capabilities by paying for the analysis of the split sample.

13.2.3 Appeals: Informing Employees of Right to Specimen Analysis

Comment:

One commenter asked whether licensees would be required to inform workers whose test results were confirmed positive that they can choose to have the original aliquot reanalyzed as well as have the split specimen analyzed at a second testing laboratory. (Identification number: 5002)

Response:

The appeal rights of workers, including their rights to reanalysis of original specimens and rights to analysis of split specimens, should be comprehensively covered in awareness training. Workers with confirmed positive test results should be made aware of their full rights regarding appeal, as required by Section 26.28, and where split specimens have been collected, by section 2.7(k) of Appendix A. Section 2.9(e) of Appendix A gives the MRO the responsibility of determining whether or not to order a reanalysis of the original specimen, and requires the MRO to order a reanalysis of a specimen if such a reanalysis is requested by the donor.

14.0 Training

The proposed revisions to the training requirements drew a number of comments. Comments addressed general awareness training and supervisory training issues.

14.1 Awareness Training

The commenters noted the advantages of consolidating the awareness and supervisor/escort training programs and requested that the NRC make changes to the training cycles for each program to accommodate such consolidation.

Comment:

Four commenters noted that some licensees have chosen to consolidate their awareness and supervisor/escort training programs so that everyone with unescorted access is trained to the highest level of knowledge and can act as an escort. Three of these commenters requested that the NRC consider adopting the same cycles for awareness and supervisor training so that the implementation and tracking of a combined training program would be simplified for those licensees who choose to consolidate the two programs. Two of the commenters also specifically recommended that the 24-month frequency for awareness training outlined in section 26.21 be extended to the training of supervisors and escorts. (Identification numbers: 7; 12; 6006; 6010)

Response:

The rule revisions for awareness and supervisor training reflect what the NRC considers to be the appropriate schedule and level of training for workers in the general plant population and for supervisors and escorts. Licensees have the flexibility to create one training cycle by training all personnel to the highest level and frequency. The importance of supervisors and escorts in assuring the effectiveness of the FFD program requires that they have a yearly refresher requirement.

14.2 Supervisory Training

Several commenters responded to the proposed rule revisions about supervisory training procedures. Responses included objections to the differences in supervisory training requirements for licensee and contractor supervisory personnel. Requests for clarification regarding these different training requirements and policies were also received from some commenters. Revisions to refresher training requirements elicited a number of questions and suggestions from commenters with regard to alternative methods of training and/or testing, frequency of training and/or testing, etc.

14.2.1 Supervisory Training: Comparability of Licensee and Contractor Supervisor Requirements

Comment:

Two commenters recommended that all supervisors, whether licensee or contractor/vendor, should have the same requirements regarding the time period for FFD training and completion. A contractor/vendor maintained that the differences between the two types of supervisor training discriminate against contractors. The Department of Nuclear Safety, State of Illinois was

concerned that in some cases, 10 days might not be sufficient time to provide training to new departmental supervisors. NEI stated that stipulating different requirements creates an unnecessary tracking burden. This commenter stated that the proposed requirements was more restrictive than circumstance warrant and suggested that initial training for all supervisors should be completed as soon as feasible before assignment to duties, routinely within 30 days, but no later than three months following assignment of supervisory duties. (Identification numbers: 7; 26; 33)

Response:

As permitted in the initial rule, licensee supervisors who are granted an initial supervisory assignment will continue to be allowed a more flexible initial training time frame of 3 months in order to prevent the possibility that promotions within the licensee's workforce might be impeded due to rigid training requirements.

The NRC believes that the shorter time limit for contractor personnel to be trained following their initial supervisory assignment is justified because of the higher rate of positive tests among contractor personnel throughout the history of the rule. The NRC also believes that training in the subject areas specified in section 26.22(a), especially in the areas of behavioral observation and initiating corrective actions, could help detect and deter the substance abuse problems with the contract workforce.

The NRC also believes that the 10 days is a reasonable period within which the training can be completed after initial assignment as a contract supervisor. The NRC recognized some of the difficulties of training contract supervisors (see 11.3.4 to 11.3.6 of NUREG-1354, which addressed rotation of supervisory responsibilities, and 3.3 of NUREG-1385, which recommended acceptance of prior training). The NRC believes that the change will help prevent situations where contract supervisors were not trained in their supervisory responsibilities, which may have contributed to the much higher rate of positive tests among contract personnel. See section 14.1 for related comments.

14.2.2 Supervisory Training: Supervisors without Unescorted Access

Comment:

One commenter disagreed with the proposed amendment that supervisors of contractor personnel need to complete training. The commenter stated that the current rule does not require training of supervisors of contract personnel unless the supervisor is granted unescorted access, and that off-site supervisors rely on licensee supervisors or job sponsors to provide supervisory oversight for the contractors. The proposed amendment would create a significant burden. (Identification number: 32)

Response:

The NRC disagrees with this interpretation of the original intent of the rule and refers to 3.10 of NUREG 1385, which states that the primary responsibility for evaluating long-term trends such as patterns of absenteeism, always lies with the supervisor of the organization to which the individual belongs. Whoever is responsible for supervising the completion of the work would be responsible for observing such behavior on site. See also Summary Comment 14.2.1.

14.2.3 Supervisory Training: Explanation of Differences in Requirements for New vs. Transferred Supervisors

Comment:

One commenter requested clarification as to why supervisory training for an employee with an initial supervisory assignment can be completed as soon as feasible but no later than three months following the assignment of supervisory duties, while a supervisor not previously performing within the scope of the rule, but then moved into a supervisory position within the FFD program must receive supervisory training before assuming duties. (Identification number: 6006)

Response:

The distinct time frames for the two types of supervisory personnel, those with an initial supervisory assignment, and those supervisors previously not acting within in the FFD program, but who are being transferred laterally into the FFD program, is made to accommodate the possibility that personnel with initial supervisory assignments may have very little lead time before their new duties are to begin. The NRC did not wish to impede promotions to supervisory status. Supervisory personnel making lateral moves into the FFD program are likely to have advance notice of this transfer and supervisory awareness training should ideally take place before the duties begin.

14.2.4 Supervisory Training: Clarification Regarding Frequency of Training

Comment:

One commenter requested clarification as to exactly when supervisor training is required for licensee supervisors and supervisors of contractors. Further clarification is also requested regarding whether the 12-month refresher training requirement includes flexibility that allows the refresher training to occur \pm 3 months as long as it is not greater than 3 months at the end of a three-year period. (Identification number: 5002)

Response:

The NRC believes that the revision to section 26.22(c) is clear about the requirements for supervisory training. See Summary Comment 14.2.3 for a more detailed explanation of the rationale behind the requirements. Supervisors' training is an important part of the NRC's FFD program and licensees are required to ensure that supervisors receive refresher training at the frequency specified by the rule. However, the NRC recognizes that not all supervisors receive their initial training at the same time. Licensees should use their best judgment in working out the timing logistics of the refresher training. The intent of the rule is that refresher training, or the specified equivalent, should occur on an annual basis. In that regard, the NRC will permit flexibility of plus or minus three months from the annual date (anniversary) as long as it is not greater than plus or minus three months at the end of a three-year period.

14.2.5 Supervisory Training: Burden Requirement of "Test-Out" Approach

Comment:

A commenter pointed out that using a "test out" approach, which allows a written examination of training materials in lieu of written training would prove more burdensome because it would require

licensees to collect, score, and retain tests as documentation. The commenter recommended that the 24-month retraining frequency outlined in section 26.21 be extended to cover section 26.22. (Identification number: 12)

Response:

The NRC is allowing a written examination that demonstrates an adequate knowledge of pertinent FFD material and issues to be used in lieu of refresher training for supervisors and escorts in two out of every three years in order to provide licensees with flexibility and reduce the burden an annual refresher course might impose. The exam in lieu of training is offered as an alternative and is not a requirement. Licensees are required to monitor the completion of refresher training by employees regardless of its form (exam or training course).

NRC disagrees with extending the intervals of supervisory training to 24 months because of the importance of supervisors and escorts in assuring the effectiveness of the FFD program.

14.2.6 Supervisory Training: Refresher Training Frequency

Comment:

Several commenters discussed the proposed requirement for a classroom supervisory refresher training every 36 months. One commenter agreed with the proposed requirement but recommended that “refresher training” include reading of training material, computer-based training and/or equivalent training techniques in addition to classroom training. Other commenters disagreed with the proposed training frequency but agreed with the first commenter that training should include alternatives to classroom work. One commenter who disagreed with the proposed requirement maintained that training or an exam every 12 months is excessively frequent and recommended that initial training be followed every 24 months by refresher training. Another commenter suggested that refresher training should only consist of an annual written exam, making refresher training consistent with plant access training. Another commenter suggested that classroom training should be considered performance-based and conducted as necessary without waiting for the training cycle anniversary. Another commenter stated no opinion about the training frequency but agreed that training should include other methodologies as well as classroom training. Another commenter interpreted “initial” and “refresher” training as written in the proposed requirement to include the use of examinations, computer-based training or other equivalent techniques. (Identification numbers: 7; 10; 15; 20; 24; 32; 6006)

Response:

The NRC appreciates the suggestion that refresher training include other types of training methods in addition to classroom training, such as reading materials, computer based training, etc. The NRC has not in the past prescribed a specific method of training and declines to add specifics regarding the method of training to the rule. The rule revision allowing a written examination in lieu of training for two out of every three years is a relaxation from the previous refresher training requirements. However, the rule stipulates that training may be provided more frequently if considered necessary. The NRC is committed to ensuring the health and safety of the public from licensee operations and believes the requirement that refresher training take place at least every three years is not unduly frequent.

14.2.7 Supervisory Training: Use of a Standardized Exam

Comment:

Another commenter requested clarification as to whether or not the annual written exam that can be used in lieu of refresher training will be a standardized exam developed by the NRC or one that is developed by the utilities. (Identification number: 6007)

Response:

The NRC will not develop a standard annual written refresher training exam, especially since it must include site-specific matters, such as the roles and responsibilities of several persons, and procedures for initiating corrective actions and making referrals to the EAP.

14.2.8 Supervisory Training: Behavioral Observation Skills

Comment:

One commenter proposed that the behavioral observation skills of utility supervisory personnel be enhanced. The commenter believed that behavioral observation is the most effective means for supervisors to ensure worker integrity and trustworthiness. If behavioral observation skills were adequate, the commenter thought there would be no need for more extensive testing procedures. (Identification number: 28)

Response:

The NRC agrees that behavioral observation, despite its shortcomings which have been described several times (see 4.2.7 of NUREG/CR-5227 and the discussion with the proposed rule published in the Federal Register on September 22, 1988 at 53 FR36807), is an important part of ensuring that employees covered by the rule are performing their tasks in a reliable and trustworthy manner. However, behavioral observation is just one component of a comprehensive fitness-for-duty program. The testing procedures are also important in order to demonstrate the effectiveness of the program, to provide deterrence, and to provide early detection of persons who are not fit to perform their duties safely and competently.

15.0 MRO Duties & Procedures, Employee Assistance Program, and Rehabilitation

Several comments were submitted regarding MRO duties and procedures, Employee Assistance Program policies and procedures, and rehabilitation issues.

15.1 MRO Issues

A wide variety of MRO related comments were received. Some issues that generated a good deal of comment include the MRO's independence from the testing laboratory, medical determination of fitness policies and procedures, policies regarding the MRO's review and subsequent management notification of test results, and MRO consultation before direct observation collection.

15.1.1 MRO Issues: Staff Performance of Routine Duties

Comment:

One commenter agreed that the MRO's staff should be allowed to perform routine administrative support functions, including receipt of test results and scheduling interviews for the MRO. (Identification number: 20)

Response:

The NRC concurs and has revised section 2.7(h)(2) accordingly.

15.1.2 MRO Issues: Independence of the MRO from the Laboratory

Comment:

Several commenters addressed the issue of independence of the MRO from the HHS-certified laboratory (see also related Summary Comment 15.1.13). Some commenters supported the new section 2.7(p)(6) of Appendix A and the revisions to section 2.9(b) of Appendix A, which require this independence. Others requested clarification that further defines the limits of the relationship between MROs and the laboratories. (Identification numbers: 6; 20; 5003; 6014)

Response:

These revisions to the rule are adaptations of changes HHS made to its Mandatory Guidelines. Changes from those guidelines are intended to assure that on-site testing features of the program are covered as well as HHS-certified laboratories. The NRC believes the rule to be sufficiently clear on the requirements regarding conflict of interest (see response to Summary Comment 15.1.13).

15.1.3 MRO Issues: Medical Determination of Fitness

Comment:

A number of commenters dealt with issues surrounding a medical determination of fitness. One commenter noted a potential discrepancy in whether there should be a medical determination of fitness or a management determination of fitness. Two commenters suggest that licensed physician/MRO should be replaced with a more general health care professional designator. One

suggested that the proposed revision to the medical determination of fitness requirement, as written, would require that the licensee employ a full time physician. (Identification numbers: 29; 36; 6019)

Response:

The NRC believes that both medical and management evaluations should be made. As discussed in section 6.2.2, the NRC continues to believe in the importance of the judgment of a licensed physician in making these determinations. The NRC does not believe that the requirements suggest the need for a full-time physician. The medical determination of fitness must be a careful evaluation of all relevant data and should not be a superficial effort whose whole purpose is to return the individual to duty before replacement personnel are called in. See also Summary Comment 6.2.

15.1.4 MRO Issues: Scope of MRO Duties in Medical Determination of Fitness

Comment:

A commenter proposed a fairly detailed change to the definition of medical determination of fitness, arguing that the current definition adds a “myriad of escalated requirements for the MRO.” Another commenter thought that the definition would involve MROs in management decision making. The same commenter suggested that more flexibility is required for licensees with regard to the determination of fitness. Another commenter noted that the requirement that an MRO make a medical determination of fitness in the five categories in section 2.9(g) of Appendix A would be burdensome for licensees. (Identification numbers: 7; 29; 32)

Response:

The MRO's duties have always included evaluation of the fitness of workers to perform safely. The definition of medical determination of fitness clarifies these duties. The MRO has also always been required to determine whether a laboratory confirmed positive test result or certain other information represents evidence of a violation of the licensee's FFD policy. It is because some licensees quickly returned workers to duty without an adequate determination of fitness that the NRC decided to clarify the rule. See also Summary Comment 6.2.

15.1.5 MRO Issues: Review of Both Positive and Negative Results

Comment:

Two commenters responded to the requirement that MROs review both positive and negative test results. They suggest that the “accounting” function of assuring that all tests are completed be done by FFD staff and that the MRO be required to review only positive results. A third commenter requested clarification regarding whether preliminary drug screen results are included in an MRO review. (Identification numbers: 7; 24; 5002)

Response:

The NRC agrees that the "accounting" function to assure that all specimens collected are tested is a function that may be performed by the MRO's staff, as permitted by section 2.7(h)(2). The NRC believes that extending this function to the FFD program staff would be inappropriate because (i) test results are required to be sent to the MRO only and (ii) the potential for a conflict of interest.

The MRO has always had access to all testing results. The HHS Mandatory Guidelines specify that all results reported by the laboratory must be reviewed at a general level by the MRO. The NRC also believes that both negative and positive results must be reviewed, but that the MRO may assign routine aspects of the review of negative results to the MRO's qualified staff. Prior to sending the test results to licensee management, the MRO, or technically qualified staff under the MRO's supervision, is expected to review the negative test results for any anomalies, false negatives (based on blind performance tests), or low specific gravity or creatinine results that indicate a need for recollection, reanalysis, etc. Positive test results, in contrast, require a careful, in-depth, individual review by the MRO. This modifies the NRC's previous position on the need for review of negative results, as set forth in item 5.8 of NUREG 1385, which incorrectly indicated that the MRO need not review negative test results and indicated that review of negative results to determine if there was a problem was discretionary. In fact, the HHS Mandatory Guidelines and the NRC's FFD rule require that all tests be sent to the MRO for review. The in-depth, specific, and individual review of findings required for all positive results is not, however, expected for all negative laboratory reports. See also Summary Comment 7.6.4.

Results of drug screening tests are not normally reviewed by the MRO unless a testing problem is being analyzed or the screening results are relevant information for determining an issue associated with abuse of a substance not in the standard testing panel such as an over-the-counter medication.

15.1.6 MRO Issues: Training and Certification Requirements

Comment:

One commenter suggested that as drug testing evolves, more responsibility is being placed on MROs. Therefore, training and certification of MRO is becoming increasingly important. (Identification number: 8)

Response:

The NRC agrees that the MRO plays a vital part in assuring an effective program and recognizes that there are currently existing certification programs intended to assure a desired level of MRO competency. While the NRC also recognizes that this may be an area requiring regulatory action in the future, it is not considering requirements regarding MRO certification at this time.

15.1.7 MRO Issues: Independence of Blind Performance Testing Specimen Providers

Comment:

In response to NRC Question 7(b), one commenter supported the potential rule revision that would require blind performance testing specimen providers to be independent from collectors, testers, and MROs. (Identification number: 18)

Response:

The NRC believes that it is not necessary at this time to require the independence of blind performance test specimen providers from the laboratory(ies) where those specimens will be tested and the MROs who will review the results. It will continue to confer with HHS regarding this issue.

15.1.8 MRO Issues: Written Notification of Results

Comment:

Two commenters objected to the proposed rule change that would require that licensees receive from MROs written notification of positive test results. One commenter noted that this practice may delay action against a violator. The second commenter was concerned with the issues of confidentiality that this requirement may raise. One commenter suggested that the licensee be given the flexibility to determine the most expeditious means for the MRO to provide notification. (Identification numbers: 21; 36)

Response:

The requirement for written notification is consistent with a similar requirement in the HHS Mandatory Guidelines. This requirement does not preclude initial notification by telephone or other means, but requires a written record of the positive test results be produced by the MRO and provided to the licensee. This can be a formatted report where specific information can be entered by hand, or it can be transmitted by electronic means (e:mail, fax, etc.) to simplify and expedite the process.

15.1.9 MRO Issues: Consultation Regarding Observed Collections

Comment:

One commenter disagreed that a medical review officer or other medical professional should be consulted before an observed collection is done as required by section 2.4(g)(24). The commenter maintained that the decision to make an observed collection should be made by the collector and/or a higher level supervisor with approval from the licensee, and a MRO or medical professional should not be consulted unless there is a "shy bladder" or other medical reason for the consultation. (Identification number: 25)

Response:

MROs or other medical professionals have been added as an alternative to higher level supervisors as individuals appropriate to approve an observed collection. As the commenter notes, there are occasions when this is appropriate.

15.1.10 MRO Issues: MRO Notification of Management

Comment:

One commenter recommended that MROs be required to report results as soon as practicable without any added provisions regarding the timely notification of management in section 26.24(f). (Identification number: 7)

Response:

The NRC continues to believe that the rule must provide some assurance that test results are provided to management within a reasonable time after specimen collection. The change to section 26.24(f) is intended to assure that MROs provide licensee management this information as soon as it is available ("as soon as practicable") and that cases in which there is some problem

with the specimen do not result in lack of notification to management for more than 14 days after specimen collection.

15.1.11 MRO Issues: Telephone Interviews

Comment:

One commenter requested advice about MROs' use of telephone interviews, rather than face-to-face interviews, to verify confirmed positive test results as FFD policy violations. The commenter wondered if telephone interviews are appropriate for this purpose in cases other than opiate positives. (Identification number: 5002)

Response:

The rule specifies that the MRO must determine whether there is reasonable and substantial clinical evidence, in addition to the urine test, for opiate positive tests. To meet this requirement, the MRO would need to look for needle tracks, or behavioral and psychological signs of acute opiate intoxication or withdrawal. This requires that the MRO personally examine the individual. To do so, the MRO must be in the same room with the individual who is being examined. As explained in NUREG 1385, in some cases not involving opiate abuse, the MRO can discuss the test results with the individual by telephone, provided suitable precautions are taken to confirm identity and protect the information as required by sections 26.29(a) and (b).

15.1.12 MRO Issues: Placement of Section 2.7(h)(2) and (h)(3)

Comment:

One commenter suggested that some of the text in section 2.7(h)(2), and the entire text of section 2.7(h)(3), be moved to section 2.9(b) because the material from sections 2.7(h)(2) and (3) deals with MRO duties. (Identification number: 36)

Response:

While these sections apply to MRO duties, they also relate to laboratory and testing analysis procedures and are appropriately provided in section 2.7.

15.1.13 MRO Issues: Independence of MROs

Comment:

One commenter asked whether a rule revision that would prohibit the MRO from being an employee of or having a financial interest in the HHS-certified laboratory or contracted on-site testing services used by the licensee should apply to MROs that licensees contract with to provide MRO services. (Identification number: 6014)

Response:

The prohibition applies to any MRO reviewing any test results of specimens collected under Part 26 regardless of whether the MRO is an employee of the licensee, an "independent" contractor, or an employee or partner in an MRO service. This requirement also encompasses any FFD program reviewed and accepted by a licensee under the provisions of section 26.23.

15.1.14 MRO Issues: Clinical Evidence of Abuse

Comment:

One commenter suggested that “clinical evidence of abuse” of opiates in section 2.9(d) be limited to needle tracks and admission of use. Another recommended that if “substantial evidence of a significant lack of reliability or trustworthiness” is also considered part of the definition of “clinical evidence,” then it should be more clearly defined. (Identification numbers: 7; 20; 6014)

Response:

The NRC agrees that "substantial evidence of a significant lack of reliability or trustworthiness" would have created difficulties and section 2.9(d) of the rule has been revised to omit these words. The NRC believes that behavioral and psychological signs of acute opiate intoxication or withdrawal should be part of clinical evidence. Admission of use has also been added to the rule as an example of evidence.

15.2 EAP Issues

A few comments were received regarding Employee Assistance Programs. One common concern was that the proposed information collection requirements might threaten the confidentiality of EAP processes. Clarification was also requested regarding the design of Employee Assistance Programs.

15.2.1 EAP Issues: Testing of EAP Personnel

Comment:

One commenter questioned the proposed requirement to test EAP personnel because, if an EAP provider tested positive, it would make maintaining confidentiality of EAP referral difficult to control. (Identification number: 1)

Response:

Modifications have been made to section 26.2(a)(4) that will clarify testing requirements for EAP personnel and other FFD program personnel. Additionally, the NRC recognizes that positive results concerning EAP personnel will be provided to EAP management. The individual can choose to be referred to a co-worker for counseling or to an "outside" provider. Therefore, the NRC does not see any reason why testing of EAP personnel performing activities covered under section 26.2 should jeopardize the confidentiality of EAP referral.

15.2.2 EAP Issues: Information Collection Requirements and Confidentiality

Comment:

One commenter suggested that the information collection requirements suggested by the NRC would threaten confidentiality of EAP results since they would include the number of referrals to the EAP, etc. Another commenter supported this view, noting that self referrals would be less likely if counselors were collecting information. (Identification numbers: 7; 29)

Response:

The NRC understands that many licensees currently collect EAP performance data, similar to those described in the May 1996 Federal Register notice, and provide monthly reports to management. The NRC is not aware of any instance where such information, which does not identify patients, has had any chilling effect on the use of the EAP. Information regarding number of workers seen and types of problems identified is usually required for billing and insurance purposes and, hence, is already being collected.

15.2.3 EAP Issues: Outsourcing of EAP Services

Comment:

One commenter noted that recent changes in outsourcing of EAP services have made it difficult to control the EAP professionals and may lead to poor understanding by EAP professionals of the specific needs of the nuclear industry. (Identification number: 6014)

Response:

The NRC recognizes that changes in health delivery and insurance may impact FFD program effectiveness. It expects licensees to recognize potential problems due to these changes and to act to prevent them from creating situations that may have a negative impact on public health and safety.

15.2.4 EAP Issues: Definition of Early Intervention

Comment:

One commenter requested clarification of the word "early" as it is used in section 26.25 regarding the design of Employee Assistance Programs. The commenter also asked for clarification about the standards to which licensees will be held as they comply with the requirement that EAPs "achieve early intervention." (Identification number: 5002)

Response:

The intent of the requirement for EAP programs to be designed to achieve early intervention is to assure employees are encouraged to self refer. For example, a policy that equates self referral to a positive drug test would be viewed as discouraging self referral. Aspects of the program, such as dependable confidentiality of self referrals, accessibility, and proven results are expected to encourage early self referral. A proven track record and support from successfully treated employees who willingly share their experiences with the workforce have also encouraged self referrals.

15.3 Rehabilitation Issues

A few comments were submitted regarding rehabilitation issues. Some concerns involved definitional issues and others referred to possible policy issues that might be raised as a result of certain wording in the proposed rule.

15.3.1 Rehabilitation Issues: Multiple Positive Test Results from a Single Use

Comment:

One commenter discussed a possible situation in which an individual is tested before the results of a previous test are known, and both test results are positive. The commenter suggested that in this situation a licensee may declare the second test to be a second positive and take appropriate action against the individual. The commenter stated that it is unlikely that such a determination could be made unequivocally. Also, the commenter maintained, if an individual is tested while still in treatment, taking action on those test results may raise labor relations issues since the individual is likely to be in a non-work or off-duty status during treatment. The commenter recommended that the words "...including during an assessment or treatment period," be deleted from section 26.27(b)(3). (Identification number: 36)

Response:

The NRC recognizes that it is possible for multiple positive test results to occur based on a single illegal drug use. For example, the worker could be selected for a random test before the results of a previous random test have been received. MROs are expected to use judgment regarding whether a second positive test in such a case is from the original or subsequent use and whether it constitutes a second violation of the program. If the individual is in treatment, a general decline in concentration levels of drugs or metabolites in the urine, even if above the cut-off level, should indicate no subsequent use has occurred. Since section 26.27(b)(2) assumes that positive drug tests are the result of off-site (e.g., off duty) drug use, the NRC does not agree that a positive drug test while in an off-duty status during treatment would present a legal impediment for taking action. Therefore, the NRC declines to delete the phrase "including during an assessment or treatment period." See Summary Comment 7.4.4.

16.0 Management Issues

A diverse set of comments about management issues were raised on proposed revisions to the rule. Issues ranged from management oversight of EAP and MRO personnel to the requirement to issue FFD policy statements to affected personnel.

16.1 Oversight Issues

One commenter requested clarification on who is the appropriate manager to report refusals to provide specimens and another commenter noted that the rule revisions appear to imply that the FFD manager has oversight of the MRO and EAP personnel.

16.1.1 Oversight Issues: "Appropriate Manager"

Comment:

One commenter requested clarification regarding whether the "appropriate manager" in section 2.4(j) of Appendix A would be the employee's manager. (Identification number: 5002)

Response:

The wording in the rule revision to this section specifies that an individual's failure to cooperate with the urine collection or breath analysis process must be reported "immediately to the MRO, the FFD Program manager, or to other management having a need to know, as appropriate, for further action." The wording in this section was changed to clarify that the "appropriate manager" may not necessarily be the employee's manager. The rule continues to provide licensees with the flexibility to make the determination as to who the appropriate decision-making managers are within their facilities. Licensees should ensure that these members of management are informed of their responsibilities in these matters.

16.1.2 Oversight Issues: Oversight of the MRO and EAP Personnel

Comment:

One commenter noted that the rule revisions seem to make the assumption that the FFD manager has oversight of the MRO and EAP personnel and noted that this is not the case at the commenter's nuclear power plant. (Identification number: 6017)

Response:

One of the fundamental aspects of the NRC's regulatory philosophy is that the licensees have the responsibility for operating their facilities, which includes determining which aspects such as MRO and EAP services will be performed by contractors or by utility employees. Licensees are responsible for managing their FFD programs including ensuring proper performance by MROs and EAP services, regardless of their contractual status. The NRC refers to the person with overall program responsibility as the FFD program manager. If FFD program responsibilities are dispersed in several organizational elements, the manager to whom all those elements report would be the FFD program manager as the NRC uses the term.

16.2 Other Managerial Responsibilities

One commenter requested clarification on the requirement to make FFD policy statements available to all individuals subject to the policies and another commenter noted that there is an apparent conflict between two statements regarding management and medical determinations of fitness for duty.

16.2.1 Other Managerial Responsibilities: Availability of FFD Policy

Comment:

One commenter requested clarification regarding how licensees are to satisfy the requirement of making a policy statement addressing FFD policies “readily available to all persons subject to the policy.” (Identification number: 20)

Response:

Because of legal considerations, it is important that all persons covered by a licensee's FFD policy clearly understand what is expected under that policy and the consequences of lack of adherence to that policy. In implementing section 26.20, licensees have made available to affected employees a summary statement of their fitness-for-duty policies in the form of brochures and posters in addition to making available the more comprehensive written policies and procedures. The NRC's purpose in adopting the new wording in section 26.20 is to codify the licensee's practices and clarify the omissions in the text in this matter. Licensees continue to be in the best position to determine the specific means of making their policy statements available to their employees. However, a convenient and timely way to ensure that licensees' policy statements are distributed to all affected personnel is distribution during awareness training. Policies that are only contained in FFD procedure manuals and not provided in a summarized format would not be readily available to employees.

16.2.2 Other Management Responsibilities: Fitness Determinations

Comment:

One commenter noted that there is a potential conflict between the requirement that an MRO or other licensed medical person make a determination of fitness for duty and a later statement that the individual is determined fit by a designated licensee representative qualified to make that determination. (Identification number: 6019)

Response:

In the interests of safety, determinations of an employee's fitness to return to duties covered by Part 26 after events that put that fitness into question should always be made jointly by both an appropriate manager and a qualified licensed physician. However, in those instances where an individual tests negative in a for-cause test, only an appropriate manager need make a determination of fitness. The Commission has decided not to adopt the requirement that a medical determination of fitness be performed to evaluate employees who test negative in a for-cause test. In situations such as preaccess and return-to-duty testing, the fitness determination is ordinarily made during normal work hours when the MRO is on-duty. By contrast, the need for a medical determination after a negative for-cause test could occur during off-normal work hours when the

MRO is not available. In this situation, the licensee would have the following options: (1) provide an MRO on a 24-hour or as-needed basis or (2) defer the medical determination until normal work hours. The added costs and reduced flexibility would only occur in negative for-cause tests, and there is insufficient data to show that such costs would be justified in terms of the identification of significant numbers of unfit workers would only be identified as unfit by the MRO. Therefore, the Commission has decided that a medical determination after a negative for-cause test is not warranted.

The NRC sees no conflict between the definition in section 26.3 of a "medical determination of fitness," and the requirement in section 26.27(b) for the fitness determination by an appropriate manager and a licensed physician.

17.0 Recordkeeping and Reporting Requirements

There was a great deal of response to the NRC's request for public comments on whether licensees should be required to collect, analyze, and submit information to the NRC to enable it to better manage its FFD program oversight responsibilities which include formulation of public policy (NRC Question #4: discussed also in 3.4 of this document). Many commenters objected to the collection of additional information for a number of reasons. Other commenters requested clarification regarding specific reporting requirements. Several commenters addressed the issue of routine program performance data (e.g., consolidation of site reporting, usefulness of the results, etc.). The effect of rule revisions on FFD policies, such as the proposed revision to retain records for five years, was also discussed. Several commenters sought clarification on specific reporting procedures. Others provided suggestions to reduce burden. Other recordkeeping and reporting requirement related issues were also raised.

17.1 Recordkeeping Requirements

Commenters raised issues regarding the proposed rule changes for additional recordkeeping information. One commenter noted a discrepancy between the record retention requirements and other requirements of the rule and requested clarification on when certain records can be destroyed.

17.1.1 Recordkeeping Requirements: Value of Additional Information

Comment:

Several commenters disagreed with the possible collection of additional information on the basis that the type of information being considered would provide no additional public health and safety protection or program value. Rather, the commenters maintained that it would create an additional administrative and financial burden on the licensees, violate EAP confidentiality and licensee and employee privacy, and contradict the Paperwork Reduction Act. A number of commenters also stated that the NRC has managed to provide sufficient oversight of the industry's FFD program over the past six years without such information and, if the information really is necessary, it can be made available upon request during inspections. Another commenter suggested that the new collection and reporting requirements must be justified as being necessary for the protection of public health and safety. (Identification numbers: 1; 7; 10; 12; 14; 15; 20; 29; 32; 36; 5001)

Response:

The NRC has determined that the types of information suggested for collection are appropriate and may, at some time, be required for the NRC to meet its oversight responsibilities. However, at this time, no additional information collection requirements, beyond those included in the rule revisions as proposed in 61 FR 21105, have been added.

17.1.2 Recordkeeping Requirements: Retaining Records for Five Years

Comment:

One commenter stated that presently the records of a FFD policy violation must be retained for five years. However, if the second offense occurs at or after five years, there would be no record of the first offense, and consequently, no basis for a 36-month removal from activities, as required

in proposed section 26.27(b)(3). The commenter asked whether section 26.71(b) would be revised to require record retention for a longer period. (Identification number: 5002)

Response:

The records that can be discarded after five years under section 26.71(b) are supporting documentation collected in determining confirmed positive test results and the related personnel actions. Section 26.27(c) has been clarified to assure that information on all FFD policy violations is retained consistent with the section 26.71(b) record retention requirements.

17.1.3 Recordkeeping Requirements: Record Retention

Comment:

One commenter asked for clarification as to when records such as negative test results, quality control records, and instrument maintenance records can be destroyed. (Identification number: 5002)

Response:

The NRC does not require that records of negative test results be retained but recommends that appropriate summary information be retained for program performance reporting purposes; electronic files, for example, would be suitable for this purpose. Section 2.7(o) of Appendix A requires records of quality control and instrument maintenance to be maintained for at least two years, and that adequate records of program integrity be retained to support the validity of positive test results.

17.2 Reporting Requirements

Commenters recommended changes to the current reporting requirements which include allowing a consolidated report from the utility, reporting program performance data annually, data collection on an as-needed basis, modifications and alternatives to the standard reporting form, and using electronic mail to submit reports. Commenters also thought that the proposed rule changes clarifying the reporting of significant events were unnecessary, the reporting of routine performance data would not be useful for improving FFD programs, and that there would be hidden costs of reporting significant events. Commenters requested clarification on who should report and when and how to report certain significant events and program performance items.

17.2.1 Reporting Requirements: Consolidation of Reports

Comment:

Commenters recommended that the current site specific reporting requirement be changed to allow a consolidated report from each utility. The commenters maintained that the current reporting requirement has not yielded any results significant to the FFD program over the past six years and, without a demonstrated need, the site specific reporting requirement should be deleted. In addition, they noted that NUREG/CR-5758 analyzes data by region, not by individual site. (Identification numbers: 7; 36; 5001)

Response:

The NRC uses information reported from each site for a number of purposes. In addition to being used to produce the annual summary report, data from program performance reports are used to track performance of each site over time, to note unusual performance at each site over time, and to identify site specific issues for follow up. These various purposes preclude the reporting of results at the utility level. Therefore, the NRC declines to permit consolidated reporting.

17.2.2 Reporting Requirements: Significant Events

Comment:

Some commenters suggested that the proposed changes to sections 26.73(a)(1) to (3) intended to clarify the reporting requirements for significant events are unnecessary. In particular, one commenter recommended that proposed section 26.73(a)(3), which requires reporting of significant fitness-for-duty events that cast doubt on the honesty and integrity of FFD program personnel, be deleted because FFD program personnel are included in significant fitness for duty event reporting requirements in section 26.73(a)(2). The commenter maintained that to single out FFD program personnel in two sections would erroneously imply that they must be watched and regulated more closely than other personnel. Another commenter agreed and suggested that the existing language, which cites examples of specific instances in which reporting to the NRC is required, is adequate. (Identification numbers: 7; 20; 26)

Response:

The NRC does not believe it is appropriate to further elaborate on what types of events should be considered "significant fitness-for-duty events." The NRC added the words "but not limited to" to the examples of such events in section 26.73(a) and declines to be more specific about reporting requirements because some licensees have in the past reported only those specific examples of events that are in the rule and ignored the requirement to report all significant FFD events (see 10.1 of NUREG-1385). Also, it is not the Commission's intention to indicate that FFD program personnel bear more attention than other people covered by the rule. The NRC has revised the originally proposed new section 26.73(a)(3) to emphasize that any act by FFD program personnel that indicates a potential threat to the integrity of a licensee's FFD program should be reported to the Commission.

17.2.3 Reporting Requirements: Annual Program Performance Requirements

Comment:

Three commenters recommended that reporting of program performance data should be on an annual basis. (Identification numbers: 10; 20; 5001)

Response:

The NRC concurs and has revised the reporting requirements of section 26.71(d) to allow reporting on either a semi-annual or an annual basis.

17.2.4 Reporting Requirements: Providing NRC with Information

Comment:

One commenter requested clarification as to who is to provide the NRC with the information on significant events involving either refusal to provide a specimen, an effort to subvert the testing process, or resignation before removal for program violation. (Identification number: 26)

Response:

These types of events are reported under section 26.71(d), unless they involve a licensed operator, supervisor, or FFD program personnel and are reported under section 26.73(a). The NRC holds each licensee responsible for its FFD program and any program it has reviewed and accepted under section 26.23.

17.2.5 Reporting Requirements: Timeliness of Program Performance Data

Comment:

One commenter maintained that the reporting of routine program performance data is of academic interest but not a sufficiently useful tool for licensees to foster improvements in their FFD programs. Furthermore, the commenter stated that the annual program performance report is not provided in a timely manner. (Identification number: 5001)

Response:

The NRC requires program performance data to evaluate the ongoing success of the program and to identify program weaknesses. The analysis provided in the annual program performance summary report is intended to allow the NRC and licensees to evaluate any program relative to industry-wide program performance. Some licensees have indicated they find the reports useful for these purposes.

17.2.6 Reporting Requirements: Performance-Based Programs

Comment:

One commenter recommended that data collection should be done as needed to support performance-based FFD programs. (Identification number: 5001)

Response:

The NRC concurs that routine data collection and analysis is the heart of any performance-based program. Increased emphasis on performance-focused programs will increase requirements for routine, ongoing data collection, of the types of data discussed in the NRC's May 1996 Federal Register notice. Having access to this information would enable the NRC to gain a clearer and more detailed understanding of the actual operation of the programs. It would be infeasible to examine the subject data during NRC inspections because the NRC conducts for-cause inspections rather than routine inspections of licensee's FFD programs. The NRC is continuing to consider the desirability of collecting additional data for these purposes.

17.2.7 Reporting Requirements: Contractor/Vendor Data

Comment:

A commenter recommended that contractor/vendor data should be reported using one category instead of the current use of two categories. In this commenter's view, the use of two categories creates an arbitrary division between short-term and long-term contractors. (Identification number: 5001)

Response:

The rule currently does not specifically require separate reporting of test results for long-term and short-term contractors. The NRC will discuss changes in the standard reporting form, which was originally developed by NUMARC (now NEI), with NEI. These discussions may include whether the separation of long- and short-term contractors will continue.

17.2.8 Reporting Requirements: Program Performance Results

Comment:

One commenter maintained that the NRC form goes beyond a regulator's need to determine compliance and suggested that licensees should be responsible for implementing regulations for health and safety and regulatory compliance and evaluating program effectiveness. The commenter suggested that additional data requirements for purposes of evaluation could result in an analysis of data that is out of context. (Identification number: 5001)

Response:

The NRC requires the routine reporting of program performance to assess both licensee and regulatory program effectiveness and to identify problem areas that may require follow-up activities by the NRC.

17.2.9 Reporting Requirements: Performance-Based Testing

Comment:

One commenter noted the industry intends to develop a proposal to shift the random testing rate from 50 percent of the population to a performance-based regime based on historical positive test result percentages and to support data collection to provide the basis for this proposal. (Identification number: 5001)

Response:

The NRC has stated previously and continues to believe that using positive random test results as a performance-based measure to determine random test rates is inappropriate because a low positive test rate may represent either an effective program that is deterring substance abuse or a program that fails to detect drug and alcohol abuse effectively.

17.2.10 Reporting Requirements: Reporting Burden

Comment:

One commenter maintained that some burdens reported to the NRC are underestimated. For example, each call to report a significant event may take only 15 minutes, but the preparation time required to compile and evaluate the necessary event information, inform management, and coordinate the call with licensing personnel may take at least an hour and this time is not included in the estimate. (Identification number: 5001)

Response:

Although the NRC did include some time for internal coordination, it did not include sufficient time for all the internal coordination and documentation described by the commenter. Therefore, an adjustment to the burden estimate for internal coordination has been increased from 15 minutes to 30 minutes.

17.2.11 Reporting Requirements: Reporting of FFD Personnel Events

Comment:

One commenter requested clarification of the definition and required reporting time frame of an event that would cast doubt on the honesty and integrity of FFD program personnel. (Identification number: 5002)

Response:

The NRC believes that licensees are capable of recognizing events that cast doubt on the honesty and integrity of FFD program personnel and declines to be more specific. The NRC also notes that since the rule was published, many licensees have construed the examples in section 26.73(a) to be all inclusive and have not reported other events not covered in these specific examples. The NRC expects that, in the future, licensees will respond to the performance expectations of the regulations rather than focusing on minimum compliance. The reporting time frame is within 24 hours of discovery.

17.2.12 Reporting Requirements: Reporting Invalid Specimens

Comment:

A commenter requested clarification as to how to report violations involving specimens determined to be invalid or of questionable validity in the program performance reports, referring specifically to an example of a specimen that was tested at the laboratory's limit of detection and found to contain THC at 4 ng/ml. (Identification number: 5002)

Response:

The program performance data reporting form was developed by NEI. The NRC will be discussing changes to the program performance reporting form with NEI to address changes required by the revisions to the rule, to include the reporting of subversion attempts by type. This and other comments will be considered in those discussions.

17.2.13 Reporting Requirements: Electronic Reporting System

Comment:

In the interest of minimizing the burden of information collection, one commenter recommended the development of an electronic mail submittal system for reporting necessary information in a standardized format. (Identification number: 5001)

Response:

The NRC has undertaken the task of initiating a rulemaking that will give licensees, applicants, and other entities the option to submit documents electronically to the NRC. The rulemaking, which will also provide the procedures for making electronic submittals, will facilitate the capture of documents into the Agency wide Documents Access and Management System which will become operational during FY2000. In addition, the NRC has no objection to NEI or another industry group creating an electronic mail system acceptable to the NRC. The NRC will be discussing changes to the program performance reporting form, which was developed by NEI, to address changes required by the revisions to the rule. This and other comments will be considered in those discussions. The NRC will continue to capitalize on information technology for improving information access, information distribution, and public interaction. However, the NRC will not eliminate paper in favor of electronic communications without full consideration of the public's ability to access information electronically.

18.0 Audits

A number of commenters provided suggestions, made requests for clarification, and presented objections regarding the proposed revisions to audit requirements. Many commenters objected to the proposed requirement that licensees are to audit nominally every 12 months those contracted services not under a licensee's direct daily supervision. Others recommended that this audit requirement continue and that licensee management should take follow-up action when corrective action is needed. Other commenters requested policy and procedural clarification, such as who can perform the audits and exactly who must be audited.

18.1 Requests for Clarification of Audit Policy

The commenters requested clarification on specifics of the auditing requirements including who is required to be audited, conditions under which other licensees' audits are acceptable, who can perform the audits, and acceptable content of the audit.

18.1.1 Requests for Clarification of Audit Policy: Audits of Contractors and Vendors

Comment:

One commenter asked for clarification as to whether audit requirements apply to contractors that provide background checks and psychological evaluations of FFD program personnel or to companies that supply FFD programs with blind performance specimens and reagents. Another commenter pointed out potential inconsistencies in the definition of "contractor and vendor" in section 26.23 and the use of those terms in section 26.80(a). (Identification number: 7; 6008)

Response:

The NRC does not intend that manufacturers of blind performance specimens be audited by licensees. The materials provided, however, must be monitored to assure their accuracy and reliability. Companies that perform background checks and psychological evaluations are also not covered by auditing requirements under Part 26, unless these companies have a FFD program that has been reviewed and accepted by the licensee under section 26.23(a). In most cases, these companies are required to be audited by section 73.56 for performing these access authorization program functions. The NRC concurs that there were inconsistencies in the definitions of "contractor" and "vendor" in section 26.3 and the use of these terms in section 26.80(a) and has edited the rule language to eliminate these inconsistencies.

18.1.2 Requests for Clarification of Audit Policy: Audit of Newly-Contracted Laboratory

Comment:

Two commenters asked whether licensees will be allowed to accept other licensees' audits of HHS-certified laboratories in cases where the licensee is required to audit a newly contracted HHS-certified laboratory after its previous laboratory loses its certification. (Identification numbers: 14; 5002)

Response:

The revisions to section 2.7(n) of Appendix A are intended to allow a licensee to accept, in the interim, another licensee's audit of an HHS-certified laboratory when its laboratory loses its certification until the licensee can perform its own audit. The NRC continues to believe that pre-award inspections and initial audits are a critical program function that cannot be abrogated to other licensees. This revision is not intended to remove the licensee's requirement to audit the new HHS-certified laboratory but to provide flexibility for continuous coverage while the licensee arranges and conducts the audit within three months.

18.1.3 Requests for Clarification of Audit Policy: Having Contractors Audit HHS-Certified Laboratories

Comment:

One commenter asked whether it is acceptable under the rule for licensees to use contractors to audit their HHS-certified laboratories. (Identification number: 6019)

Response:

It is appropriate to use contractors with the appropriate specific skills in performing the audit. The licensee, however, remains responsible for the quality and completeness of audit activities. Also see 17.3.1 of NUREG 1354.

18.1.4 Requests for Clarification of Audit Policy: Auditing HHS-Certified Laboratories Used in Appeals

Comment:

One commenter asked whether the requirement of annual audits of HHS-certified laboratories applies to the "different" HHS-certified laboratories that are to be used for testing split specimens in appeals. (Identification number: 14)

Response:

Licensees are not required to audit an HHS-certified laboratory that may be selected by workers for testing their split specimen.

18.1.5 Requests for Clarification of Audit Policy: Scope of Audit of HHS-Certified Laboratories

Comment:

One commenter asked whether the requirement of annual audits of HHS-certified laboratories can be focused only on program areas that fall outside the HHS certification process. (Identification number: 14)

Response:

The licensee audit may review the HHS certification documentation in lieu of an independent audit of the areas covered by the certification.

18.2 Other Audit Issues

Commenters expressed opinions on other audit-related issues including the requirement to audit in general, as well as specific current or suggested requirements to audit every 12 months, to audit changes in procedures or personnel, and to report unfavorable conditions and recommend corrective actions.

18.2.1 Other Audit Issues: Auditing Requirements as Duplication of SAMHSA Auditing

Comment:

Several commenters objected to the proposed new wording that would clarify that licensees must continue to audit nominally every 12 months “testing performed at HHS-certified laboratories.” The auditing of HHS-certified laboratories under the Substance Abuse and Mental Health Services Administration (SAMHSA) laboratory certification program was the reason most often cited for this objection. (Identification numbers: 7; 10; 12; 14; 20; 23; 5002; 6004; 6017; 6018)

Response:

The NRC’s FFD rule provides licensees flexibility to establish lower cut-off levels than specified by HHS, to test for additional drugs, to determine specimen validity, and to use special processing, among other things. These deviations from the HHS Mandatory Guidelines are not covered by the National Laboratory Certification inspection and proficiency programs. The NRC is aware of numerous examples of significant deviations and deficiencies in testing discovered by licensees during their audits beyond those covered by the HHS certification program. Licensee audits have also discovered problems in areas subject to HHS inspections such as cut-off levels, confirmation testing, and sample handling. Also, senior officials at several certified laboratories have volunteered information to the Commission that the licensees’ audits have been very professional and have made significant findings that resulted in improvements to the quality of the laboratories’ work. The NRC, therefore, continues to believe that licensee audits of the HHS-certified laboratories are an important element of a reliable FFD program which is expected to produce consistent, valid results. The revision to the rule clarifies that those elements of the HHS laboratory that are audited by HHS do not have to be re-audited by the licensee. Instead, licensees should consider auditing these elements and must at least obtain and review the HHS audit report as part of their audits.

18.2.2 Other Audit Issues: Auditing Requirements as Supplement to SAMHSA Auditing

Comment:

One commenter recommended that the NRC continue to require licensees to audit services provided them by HHS-certified laboratories. This auditing is necessary because some testing permitted by the NRC deviates from testing required by the HHS Mandatory Guidelines (see 18.1) and, therefore, is not covered by the SAMHSA National Laboratory certification audit program. (Identification number: 8)

Response:

The NRC concurs.

18.2.3 Other Audit Issues: Requirement of Corrective Action

Comment:

One commenter recommended that the language from Appendix B to Part 50 be added to section 26.80(a) to clearly require corrective action, since the current rule requires only documentation of corrective actions. The language would provide further emphasis that licensee audit reports must identify conditions adverse to proper FFD program performance and recommend corrective action. (Identification number: 3)

Response:

A minor administrative change has been made by inserting two sentences that paraphrase audit requirements in Appendix B to Part 50 in section 26.80(c), as recommended.

18.2.4 Other Audit Issues: Audits of Changed Program Elements

Comment:

One licensee urged the NRC to provide relief from the requirement that licensees audit program elements affected by changes in procedures or personnel on the grounds that licensees' quality assurance/quality control procedures eliminate the need for such auditing. (Identification number: 6010)

Response:

If the licensee's quality assurance and quality control procedures effectively evaluate and assure the quality of the program after changes in procedures or personnel, then that QA/QC process should meet the requirements for an audit of the changes.

19.0 Rule Revision and Implementation Issues

A large number of comments were submitted regarding implementation of some of the proposed rule revisions. These comments addressed the effects the proposed revisions would have on program effectiveness, whether or not the rulemaking constituted a backfit, and the cost/benefit issues associated with the rulemaking.

19.1 Implementation of Revised Rule

Several commenters responded to the NRC's request for input regarding whether or not proposed revisions would provide an increase in the overall protection of the public health and safety and reduce burdens, including costs of rule implementation. Others addressed implementation issues and provided comments on alternatives to the rulemaking.

19.1.1 Implementation of Revised Rule: Alternatives to Rulemaking

Comment:

Two conflicting opinions were expressed regarding whether there were alternatives to rulemaking. One commenter noted that the rule revision package was the most efficient means of achieving the NRC's objectives. This idea was supported by other commenters who stated that the rule revisions would create significant cost savings, reduce regulatory burden, and increase the clarity of the rule. On the other hand, one commenter stated that while desirable, the effects of the rule revisions could be achieved by other means that would not require the promulgation of the rule (i.e., development of regulatory or industry-sponsored guidance). (Identification numbers: 3; 7; 17; 23; 27; 6006)

Response:

The NRC has concluded that rulemaking is the only effective vehicle for achieving its purposes in this instance. Rule change is favored because clear regulatory requirements eliminate interpretive debates. Collective bargaining and judicial reviews also require clear public policy in this area.

19.1.2 Implementation of Revised Rule: Implementation Difficulties

Comment:

One commenter noted that certain changes would be difficult to implement and would be so complicated that they would not achieve the desired reductions in burden. (Identification number: 7)

Response:

The proposed rule revisions have been reviewed in response to this comment and some changes have been made to reduce potentially complicated processes. The NRC noted that several examples given by the commenters introduced complications not suggested by the rule revisions. In these cases, clarification of the intent of the revision has been provided. In many cases the examples given represented reductions in burden and licensees can continue with their current program if the implementation of the burden reduction is too cumbersome.

19.1.3 Implementation of Revised Rule: General Support of Rule Revisions

Comment:

Several commenters generally favored the proposed rule changes, noting that the changes will enhance the clarity, effectiveness, efficiency, and integrity of the rule and will improve the general administration of the FFD Program. Commenters suggested that the changes be finalized as soon as possible. (Identification numbers: 3; 10; 14; 19; 29)

Response:

As a Federal regulatory agency, the NRC must comply with a significant number of regulations, considerations, and administrative procedures in the finalization of any rule package. This comment and response effort is but one such requirement. Nevertheless, the NRC will strive to complete the rule revision process as soon as possible.

19.1.4 Implementation of Revised Rule: Efficient and Effective Meeting of Objectives

Comment:

One commenter stated that the proposed rule changes would not achieve in the most efficient and effective way the objectives of reduction of cost of rule implementation, program enhancement, and continued protection of public health and safety. (Identification number: 17)

Response:

The NRC recognizes that alternative approaches may have merit and has responded to suggested changes which may better meet the objectives mentioned.

19.2 Backfit

A number of commenters addressed whether or not the revised rule constitutes a backfit. Many commenters discussed specific revisions that they considered to be backfit issues. Others addressed the rule as whole. Several commenters responded that the proposed changes would not provide a substantial increase in overall protection to public health and safety and, thus, do constitute a backfit. Others disagreed, stating that overall the rule changes represent a decrease in burden and therefore do not constitute a backfit. The following comment summaries and responses supplement those addressed in section 3.1 of this document.

19.2.1 Backfit: Suitable Inquiry Requirements

Comment:

One commenter questioned whether or not the proposed rule changes regarding suitable inquiry requirements constitute a backfit. (Identification number: 5002)

Response:

The rule has always required licensees to conduct suitable inquiries of applicants for unescorted access. See the discussion of this comment included in the discussion of the change to Section 26.27(a) in the Group IIB of the “Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26).”

19.2.2 Backfit: Increase in Licensee Burden

Comment:

Two commenters stated that overall the changes would provide an increase in the general protection of the public health and safety. One of these commenters noted, however, that some proposed revisions would increase burden without any foreseen benefit to public safety. Examples of these included actions that would be required if MROs or EAP counselors are subject to testing and test positive, tracking of persons not subject to random testing, back extrapolation for alcohol, and tracking of possible new information collections. (Identification numbers: 1; 8)

Response:

The NRC agrees with these commenters' assessment that the rule revisions will increase the rule's protection of public health and safety. See the responses to NRC questions 1(a) and 1(b), Item 3.1, above.

19.2.3 Backfit: No Substantial Increase in Public Health and Safety

Comment:

Several commenters concurred with the NRC staff's assessment that these changes, whether considered as a whole or individually, would not provide a substantial increase in overall protection of public health and safety. However, three commenters supported the proposed changes as providing some benefits including clarification, reducing burden while enhancing the objectives of the program, ensuring compatibility with the HHS Mandatory Guidelines, and strengthening of the alcohol and drug testing procedures. One of the commenters urged the NRC to go forward with the rulemaking without further backfit analysis as long as public comments are sufficiently considered. (Identification numbers: 7; 10; 12; 14; 18; 20; 30; 32; 5002; 6006)

Response:

The Commission has evaluated the changes in the final FFD rule both individually and in the aggregate as an integrated rule. The Commission concludes that, in either mode of analysis, the FFD rule constitutes a substantial increase in protection to public health and safety and that the costs of the rule are justified in light of this increase. This finding and its bases are discussed in the “Backfit Analysis” of the Statement of Considerations for the final FFD rule, the “Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26),” and the “Final Regulatory Analysis.” All of these documents are available for inspection and copying for a fee at the NRC Public Document Room.

19.2.4 Backfit: Two-Phase Rulemaking

Comment:

Several commenters supported most of the proposed rule revisions, particularly those that would produce consistency with the HHS Mandatory Guidelines and delete marginally effective requirements. Commenters recommended that the NRC enact these rule revisions promptly. In these commenters' opinion, the adoption of such changes does not require an exception to the backfit rule because no new burden would be imposed on licensees. All of these commenters, however, stated that some of the proposed rule revisions would create more than an incidental burden on licensees. For these, the NRC must comply with the backfit rule and must find that there will be a "substantial increase" in safety resulting from these proposed revisions. Several of these commenters proposed that grouping the proposed changes could be an effective approach to addressing new requirements and meeting the backfit regulations. Commenters suggested that the best approach would be to segregate those revisions that represent reductions in requirements from those that impose new requirements. Changes considered backfits should be withdrawn from the current package and, if still considered desirable by the NRC staff, processed for separate promulgation with appropriate justification. (Identification numbers: 7; 10; 11; 13; 14; 15; 27; 29; 6004)

Response:

The NRC has considered and rejected the suggestion that separate rulemaking packages be put forward as that approach is inefficient and inappropriate due to the interrelationship of changes and the additional resources and time needed. It would not have served any purpose to re-submit a subset of the changes in a separate rulemaking activity.

19.2.5 Backfit: No Backfit Analysis Required

Comment:

Two commenters stated that the backfit rule should not be applied to the proposed rule revisions. Commenters stated that, although the rulemaking as a whole provides an incremental improvement in the protection of the public health and safety, the cumulative effect of the rulemaking is to reduce licensee burdens and to significantly improve the effectiveness of the program. The proposed rulemaking, therefore, does not constitute a backfit. (Identification numbers: 3; 8)

Response:

The NRC concluded that an analysis of the changes with respect to backfitting should be conducted.

19.2.6 Backfit: Application of Backfit Analysis to Fitness-for-Duty Programs

Comment:

One commenter expressed concern over the application of a backfit analysis to fitness for duty programs. The commenter noted that FFD programs need to keep pace with changes in drug abuse patterns, methods of drug detection avoidance, and new technology. Without refinement, drug testing programs will quickly become obsolete, ineffective, and unjustifiable. In this

commenter's opinion, the backfit analysis presents an unfortunate obstacle to modifying drug and alcohol testing programs. Almost by definition, a backfit analysis requires that a program must come close to becoming ineffectual before regulatory changes can be made. As desirable as backfit analysis may be otherwise, its application in a safety program can be quite counterproductive. This commenter stated that safety programs should not have to run to the brink of failure before corrective action can be taken. (Identification number: 8)

Response:

The Commission considered this issue carefully and revisited the backfit issue in 1992 and 1993 because of its concern that 10 CFR 50.109 (the backfit rule) presented difficulties where seemingly worthwhile changes, such as the proposed changes to the FFD rule, cannot be shown to result in "substantial increase in the overall protection...". NRC staff presented its recommendations on this issue in SECY 92-308. By memorandum of June 30, 1993, the Commission announced its conclusions: the backfit rule should be administered flexibly; the "substantial increase" requirement is not intended to result in disapprovals of worthwhile improvements; and qualitative arguments can be advanced to demonstrate a "substantial increase in the overall protection....".

19.2.7 Backfit: Non-Mandatory Requirements

Comment:

One commenter thought that an improved regulation would not be constrained by the backfit rule if the NRC promulgates the regulation or portions of it as an alternative to the existing regulation. In that case, licensees would be free to elect either to continue to comply with the existing provisions or to voluntarily choose to comply with the new provisions. If the NRC does not make the new requirements mandatory, this commenter believed, the backfit rule would not come into play. (Identification number: 13)

Response:

The Commission agrees that voluntary alternatives would not constitute "backfitting" as defined in the Backfit Rule. However, the Commission has determined that an analysis of the changes in the final FFD rule should be performed, and therefore does not rely upon the voluntary nature of some provisions of the FFD rule for purposes of complying with the requirements of the Backfit Rule..

19.2.8 Backfit: Use of Qualitative Factors to Determine Whether Backfits Would Create a Substantial Increase in Protection

Comment:

One commenter advised that, in determining whether a proposed backfit will produce a "substantial increase" in overall protection, the NRC should not be limited to using a strict quantitative cost-benefit approach. The NRC should take into account appropriate qualitative factors that lead to an increase in overall safety. (Identification number: 13)

Response:

As indicated in response 19.2.6, the NRC has previously determined that qualitative arguments can be used to demonstrate that proposed rules would substantially increase public safety.

Appendix A Numerical List of Commenters

Identification #	Name/Title Affiliation/Address
1 Hanse, Amy L. Manager, FTI Access Control	Framatome Technologies 155 Mill Ridge Road P.O. Box 10935 Lynchburg, VA 24502-0935
2 Aromando, Jr., Robert L. International Marketing Manager	Roche Diagnostic Systems, Inc. Drug Abuse Testing Business Unit Branchburg Township 1080 U.S. Highway 202 Somerville, NJ 08876-3771
3 Bush, Loren	7716 Falstaff Court McLean, VA 22101
4 Morey, Dave Vice President, Farley Project	Southern Nuclear Operating Company P.O. Box 1295 Birmingham, AL 35201
5 Holker, Colleen L., MLT (ASCP) Medical Services	Northern States Power Company 2807 Highway 75 West Monticello, MN 55362
6 Smith, Vana L., PhD Chair, Government Affairs Committee	Substance Abuse Program Administrators Association 1926 Waukegan Road Suite 1 Glenview, IL 60025
7 Beedle, Ralph E. Senior VP & Chief Nuclear Officer	Nuclear Energy Institute 1776 I Street, NW Suite 400 Washington, DC 20006-3708
8 Shults, Theodore F., MS, JD Chairman	American Association of Medical Review Officers P.O. Box 12873 Research Triangle Park, NC 27709
9 Anderson, Dr. Richard Director, Governmental Affairs	Biosite Diagnostics 11030 Roselle Street San Diego, CA 92121

- 10 Cruse, Charles H.
Vice President, Nuclear Energy
Baltimore Gas and Electric Company
Calvert Cliffs Nuclear Power Plant
1650 Calvert Cliffs Parkway
Lusby, MD 20657
- 11 Hogan, Kristina A.
Key Account Manager
National Draeger, Inc.
Breathalyzer Division
185 Suttle Street
Suite 105
Durango, CO 81301-7911
- 12 Noel, J. L.
Manager, Security Training & Compliance
Babcock & Wilcox
Naval Nuclear Fuel Division
P.O. Box 785
Lynchburg, VA 24505-0785
- 13 Stenger, Daniel F. and Kathryn M. Sutton
Representing NUBARG
Winston & Strawn
1400 L Street, N.W.
Washington, DC 20005-3502
- 14 Swartz, Harry M.
Licensing Engineer
Maine Yankee Atomic Power Company
Licensing & Engineering Support Department
329 Bath Road
Brunswick, ME 04011
- 15 Brons, John C.
Vice President, Nuclear Support
Commonwealth Edison Company
1400 Opus Place
Downers Grove, IL 60515-5701
- 16 Medling, E. Scott
Manager, Regulatory Projects
Southern California Edison Company
P.O. Box 128
San Clemente, CA 92674-0128
- 17 Barry, J. J.
International President
International Brotherhood of Electrical Workers
1125 Fifteenth Street, NW
Washington, DC 20005
- 18 Willette, Robert E., PhD
President
DuoResearch, Inc.
2419 East Fifth Avenue
Denver, CO 80206-4217
- 19 Cooper, Homer F.
Entergy
No address given.
- 20 Walt, T. D.
Manager, Performance, Evaluation &
Regulatory Affairs
Carolina Power & Light Company
No address provided.
- 21 Jain, Sushil C.
Division Vice President, Nuclear Services
Duquesne Light Company
Beaver Valley Power Station

- P.O. Box 4
Shippingport, PA 15077-0004
- 22 Patterson, T. L.
Division Manager, Nuclear Operations
Omaha Public Power District
444 South 16th Street Mall
Omaha, NE 68102-2247
- 23 Bennet, Jr., Thomas W.
Vice President, Treasurer & CFO
Yankee Atomic Electric Company
580 Main Street
Bolton, MA 01740-1398
- 24 Terry, C. Lance
Group Vice President
TU Electric
Energy Plaza
1601 Bryan Street
Dallas, TX 75201-3411
- 25 Autry, III, Joseph H., MD
Director, Division of Workplace Programs
Department of Health & Human Services
Substance Abuse and Mental Health
Services Administration
Rockville, MD 20857
- 26 Ortciger, Thomas W.
Director
State of Illinois
Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704
- 27 Miserendino, George
Manager, Security Services
Northern States Power Company
414 Nicollet Mall
Minneapolis, MN 55401
- 28 Gerrity, Chip
Business Agent, IBEW LU 94
International Brotherhood of Electrical Workers
219 Franklin Street
Hightstown, NJ 08520
- 29 Stewart, William L.
Executive Vice President
Arizona Public Service
Palo Verde Nuclear Generating Station
P.O. Box 52034
Phoenix, AZ 85072-2034
- 30 Maxin, Andrew M.
Vice President, Safety & Regulatory
Management
Nuclear Fuel Services, Inc.
1205 Banner Hill Road
Erwin, TN 37650
- 31 Saunders, Robert F.
Vice President, Nuclear Operations
Virginia Power
Innsbrook Technical Center
5000 Dominion Boulevard
Glen Allen, VA 23060
- 32 Tuckman, M. S.
Senior Vice President,
Duke Power Company
P.O. Box 1006

	Nuclear Generation	Charlotte, NC 28201-1006
33	Edgar, James B. Staff Engineer, Licensing	Siemens Power Corporation 2101 Horn Rapids Road Richland, WA 99352
34	Beckham, Jr., J. T. Vice President, Nuclear, Hatch Project	Georgia Power Company 40 Inverness Center Parkway P.O. Box 1295 Birmingham, AL 35201
35	Singer, Donald A., MD	Western Pathology Consultants, P.C. 211 W. 39th Street Scottsbluff, NE 69361
36	Hunger, Jr., G. A. Director, Licensing	PECO Energy Company Nuclear Group Headquarters 965 Chesterbrook Boulevard Wayne, PA 19087-5691
5001	Tipton, Thomas E. Vice President, Operations & Engineering	Nuclear Energy Institute 1776 I Street, NW Suite 400 Washington, DC 20006-3708
5002	Region I FFD Association Meeting, 5/16/96	
5003	Shults, Theodore F., MS, JD Chair, AAMRO	MRO Alert, July 1996, Vol. 7, No. 6 (Supplement to Identification #8) "The Nuclear Regulatory Commission Proposes Amendments to the Drug and Alcohol Testing Program"
6004	Enkeboll, Richard	Nuclear Energy Institute Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD
6005	Holleman, Joyce	Baltimore Gas and Electric Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD

6006	Noel, James	Babcock and Wilcox Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD
6007	Warner, Tara	Framatome Technologies Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD
6008	Sears, Russell	Entergy Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD
6009	Reed, Harold	Entergy Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD
6010	Toleski, Gary	Commonwealth Edison Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD
6011	Blue, Sharon	Southern California Edison, San Onofre Plant Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD
6013	Schultz, Ted Chairman	American Association of Medical Review Officers Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD
6014	Broxson, April	Southern Nuclear Operating Company Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD
6015	Ervin, Nancy	U.S. Nuclear Regulatory Commission Public Meeting, 6/12/96 Doubletree Hotel Rockville, Plaza Room I-II Rockville, MD

6016 Paul, Will
International Brotherhood of Electrical Workers
Union
Public Meeting, 6/12/96
Doubletree Hotel Rockville, Plaza Room I-II
Rockville, MD

6017 Catchpole, Ken
Florida Power Corporation
Public Meeting, 6/12/96
Doubletree Hotel Rockville, Plaza Room I-II
Rockville, MD

6018 Brown, Diana
Houston Lighting and Power
Public Meeting, 6/12/96
Doubletree Hotel Rockville, Plaza Room I-II
Rockville, MD

6019 Gittin, John
Southern Nuclear Operating Company
Public Meeting, 6/12/96
Doubletree Hotel Rockville, Plaza Room I-II
Rockville, MD

6020 Schoenig, Bob
Drug Testing Consultants
Public Meeting, 6/12/96
Doubletree Hotel Rockville, Plaza Room I-II
Rockville, MD

6021 Anderson, Dr. Richard
Biosite Diagnostics
Public Meeting, 6/12/96
Doubletree Hotel Rockville, Plaza Room I-II
Rockville, MD

6022 Ryan, Bill
Pacific Gas Electric Company
Public Meeting, 6/12/96
Doubletree Hotel Rockville, Plaza Room I-II
Rockville, MD

6023 Brazil, Scott
Virginia Power
Public Meeting 6/12/96
Doubletree Hotel Rockville, Plaza Room I-II
Rockville, MD

Appendix B Alphabetical List of Commenters

Name/Organization	Identification #	Section(s) Where Comment(s) Addressed							
Anderson, Dr. Richard Diagnostics	9	3.6 9.3.2	4.1.7 9.3.3	4.2.6 11.4.4	9.1.1	9.2.1	9.3.1		Biosite
Anderson, Dr. Richard Biosite Diagnostics	6021	9.1.1	9.3.2	9.4.8					
Aromando, Jr., Robert L. Roche Diagnostic Systems, Inc.	2	9.1.1							
Autry, III, Joseph H., MD Department of Health & Human Services	25	3.2 4.2.2 7.6.5 9.5.1 11.1.8 15.1.9	3.5 4.2.3 7.6.7 9.5.3 11.2.1	3.6 6.3.5 9.1.1 9.5.6 11.2.5	3.7 6.3.9 9.3.4 9.5.7 11.3.1	3.8 6.5.1 9.4.1 9.5.10 11.3.2	4.1.5 7.6.4 9.4.2 11.1.4 13.1.4		
Barry, J. J. Brotherhood of Electrical Workers	17	3.1 9.3.4 19.1.1	3.5 9.5.9 19.1.4	5.1.2 10.2.1	7.2.3 11.1.8	7.3.1 12.1.2	7.6.3 12.2.3		International
Beckham, Jr., J. T. Georgia Power Company	34	4.3.1							
Beedle, Ralph E. Nuclear Energy Institute	7	3.1 3.7 4.2.8 6.2.1 7.1.4 7.4.1 7.6.5 9.3.1 9.4.6 10.3.1 11.2.3 11.4.4 13.2.1 15.1.10 18.1.1	3.2 3.8 4.2.9 6.3.2 7.1.8 7.4.3 7.6.6 9.3.2 9.4.8 10.3.3 11.2.5 11.4.9 14.1 15.1.14 18.2.1	3.3 4.3.2 6.3.4 7.2.1 7.5.1 7.6.11 9.4.1 9.5.6 11.1.1 11.2.10 12.1.3 14.2.1 15.2.2 19.1.1	3.4 4.1.2 5.2.1 6.5.3 7.2.5 7.6.2 8.1.2 9.4.2 10.1.1 11.1.8 11.3.2 12.2.2 14.2.6 17.1.1 19.1.2	3.5 4.2.1 5.2.2 7.1.1 7.3.2 7.6.3 8.2.1 9.4.3 10.1.2 11.2.1 11.4.1 12.2.3 15.1.4 17.2.1 19.2.3	3.6 4.2.6 6.1.1 7.1.3 7.3.4 7.6.4 9.1.1 9.4.4 10.2.1 11.2.2 11.4.2 13.1.1 15.1.5 17.2.2 19.2.4		
Bennet, Jr., Thomas W. Atomic Electric Company	23	3.6 9.3.1 11.4.9	4.1.5 10.2.1 13.1.3	4.3.1 10.3.1 18.2.	7.2.1 10.3.4 19.1.1	7.3.4 11.3.2	7.5.3 11.4.5		Yankee

<i>Name/Organization</i>	<i>Identification #</i>	<i>Section(s) Where Comment(s) Addressed</i>																																															
Blue, Sharon Southern California Edison, San Onofre Plant	6011	3.5	3.6	4.1.2	4.1.4	5.2.1	7.2.1	9.1.1	9.4.4	9.4.6	9.4.8	10.2.1	10.3.1	11.1.6	11.2.2	11.2.11	11.3.2	11.4.9	12.3.2	13.1.6	13.1.7																												
Brazil, Scott Virginia Power	6023	5.2.2																																															
Brons, John C. Commonwealth Edison Company	15	3.4	3.8	3.9.3	4.3.1	7.1.1	7.1.3	7.1.4	7.2.1	7.4.2	7.4.9	9.1.1	10.1.2	10.2.1	10.3.1	10.3.3	11.3.2	12.2.3	14.2.6	17.1.1	19.2.4																												
Brown, Diana Houston Lighting and Power	6018	18.2.1																																															
Broxson, April Southern Nuclear Operating Company	6014	3.5	3.6	7.3.8	9.1.1	9.3.1	10.2.1	11.1.7	11.2.8	11.2.11	13.2.2	15.1.2	15.1.12	15.1.14	15.2.3																																		
Bush, Loren	3	3.1	3.2	4.2.1	8.1.2	9.5.1	18.2.3	19.1.1	19.1.3	19.2.5																																							
Catchpole, Ken Florida Power Corporation	6017	3.5	5.2.1	10.2.1	11.1.1	11.1.2	16.1.2	18.2.1																																									
Cooper, Homer F. Entergy	19	4.3.1	19.1.3																																														
Cruse, Charles H. Baltimore Gas and Electric Company	10	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	4.1.2	4.1.7	4.2.2	4.2.4	5.2.1	5.2.3	6.3.1	6.3.7	6.3.8	6.4.2	7.1.4	7.2.1	8.1.2	9.1.1	9.3.1	9.4.1	9.4.2	9.4.8	9.4.10	10.1.1	10.2.1	10.2.4	11.1.1	11.1.2	11.1.3	11.1.5	11.2.2	11.2.4	11.3.1	11.4.5	11.4.9	12.1.1	12.2.3	13.1.1	14.2.6	17.1.1	17.2.3	18.2.1	19.1.3	19.2.3
19.2.4																																																	
Edgar, James B. Siemens Power Corporation	33	7.1.6	14.2.1																																														
Enkeboll, Richard Nuclear Energy Institute	6004	5.2.2	7.1.1	8.1.2	9.4.3	10.3.1	18.2.1	19.2.4																																									
Ervin, Nancy U.S. Nuclear Regulatory Commission	6015	8.1.2																																															

<i>Name/Organization</i>	<i>Identification #</i>	<i>Section(s) Where Comment(s) Addressed</i>								
Gerrity, Chip Brotherhood of Electrical Workers	28	3.5 7.6.8 12.2.3	4.3.3 7.7.1 14.2.8	7.2.1 9.3.3	7.3.4 9.5.8	7.6.3 10.2.1	7.6.6 11.2.1	International		
Gittin, John Southern Nuclear Operating Company	6019	4.1.1	7.3.4	11.3.2	15.1.3	16.2.2	18.1.3			
Hanse, Amy L. Technologies	1	3.1 10.2.1	5.2.2 12.2.1	7.2.1 15.2.1	7.2.2 17.1.1	7.6.1 19.2.2	8.1.1	Framatome		
Hogan, Kristina A. National Draeger, Inc.	11	3.3	10.1.1	10.1.2	19.2.4					
Holker, Colleen L., MLT (ASCP) Northern States Power Company	5	4.1.1	7.4.1							
Holleman, Joyce Baltimore Gas and Electric	6005	3.5 7.2.5 10.2.3	4.1.7 7.6.4 11.1.3	4.2.4 7.7.2 11.3.1	5.2.2 9.4.1 12.1.1	6.3.1 9.4.10	7.2.1 10.2.1			
Hunger, Jr., G. A. PECO Energy Company	36	3.5 6.2.1 7.1.1 7.3.2 7.5.2 7.6.7 9.4.1 11.2.2 11.3.5 15.1.8	3.6 6.3.3 7.1.2 7.3.4 7.5.4 7.7.3 9.5.1 11.2.7 11.4.8 15.1.12	3.9.4 6.3.6 7.1.3 7.3.7 7.5.6 9.2.2 9.5.5 11.2.8 11.4.10 15.3.1	4.1.7 6.3.8 7.1.4 7.3.8 7.6.4 9.3.1 10.1.2 11.3.1 12.2.2 15.1.1	4.3.1 6.4.1 7.2.1 7.4.4 7.6.5 9.3.4 10.1.3 11.3.2 13.2.2 17.1.1	5.2.4 6.5.2 7.2.5 7.5.1 7.6.6 9.3.6 10.1.4 11.3.4 15.1.3 17.2.1			
Jain, Sushil C. Duquesne Light Company	21	4.3.1 13.2.2	7.2.1 15.1.8	7.3.3	7.6.4	7.6.6	12.2.2			
Maxin, Andrew M. Nuclear Fuel Services, Inc.	30	3.1 7.6.11 13.2.2	3.2 9.5.4 19.2.3	4.2.1 9.5.5	5.2.2 9.5.6	7.6.2 10.2.2	7.6.9 10.3.5			
Medling, E. Scott Southern California Edison Company	16	4.3.1								
Miserendino, George Northern States Power Company	27	3.1	4.3.1	19.1.1	19.2.4					
Morey, Dave Southern Nuclear Operating Company	4	4.3.1								
Noel, James and Wilcox	6006	3.1 7.4.6	4.3.2 7.4.7	5.2.2 7.4.8	5.2.4 7.6.2	7.2.1 9.4.1	7.2.2 11.1.8	Babcock		

<i>Name/Organization</i>	<i>Identification #</i>	<i>Section(s) Where Comment(s) Addressed</i>							
		11.1.9	11.2.9	12.2.5	14.1	14.2.3	14.2.6		
		19.1.1	19.2.3						
Noel, J. L. Babcock & Wilcox	12	3.1	3.2	4.1.1	5.2.1	7.2.1	7.3.3		
		10.2.1	14.1	14.2.5	17.1.1	18.2.1	19.2.3		
Ortciger, Thomas W. State of Illinois	26	5.2.1	5.3.1	6.4.2	14.2.1	17.2.2	17.2.4		
Patterson, T. L. Omaha Public Power District	22	4.3.1							
Paul, Will International Brotherhood of Electrical Workers Union	6016	5.1.1							
Reed, Harold Entergy	6009	5.2.1	7.1.8	7.4.9	10.3.1				
Region I FFD Association Meeting,	5002	3.5	3.6	4.1.2	4.1.3	5.2.2	5.3.2		
		6.1.2	6.2.1	7.1.7	7.2.2	7.2.4	7.3.1		
		7.3.4	7.3.5	7.3.6	7.4.5	7.5.3	7.5.5		
		7.6.1	7.6.8	7.6.9	7.6.11	8.1.2	8.2.3		
		8.2.4	8.2.6	9.3.4	9.4.1	9.4.9	9.5.1		
		9.5.2	9.5.6	10.1.5	10.2.3	10.3.5	11.1.2		
		11.1.4	11.1.9	11.2.7	11.2.8	11.2.9	11.3.3		
		11.4.6	11.4.8	11.4.9	12.2.4	12.2.5	12.3.3		
		13.1.5	13.2.1	13.2.3	13.1.8	14.2.4	15.1.5		
		15.1.11	15.2.4	16.1.1	17.1.2	17.1.3	17.2.11		
		17.2.12	18.1.2	18.2.1	19.2.1	19.2.3			
Ryan, Bill Pacific Gas Electric Company	6022	7.2.6							
Saunders, Robert F. Virginia Power	31	4.3.1							
Schoenig, Bob Drug Testing Consultants	6020	11.3.2							
Schultz, Ted American Association of Medical Review Officers	6013	3.9.3	10.2.2	10.3.1	11.1.10				
Sears, Russell Entergy	6008	6.5.3	8.2.5	8.2.6	9.4.7	18.1.1			
Shults, Theodore F., MS, JD American Association of Medical Review Officers	8	4.1.6	10.2.1	10.2.2	10.2.3	11.4.3	12.3.1		
		15.1.6	18.2.2	19.2.2	19.2.5	19.2.6			

<i>Name/Organization</i>	<i>Identification #</i>	<i>Section(s) Where Comment(s) Addressed</i>											
Shults, Theodore F., MS, JD MRO Alert, July 1996, Vol. 7, No. 6 Supplement to Identification #8)	5003	4.1.8	4.3.2	4.3.4	9.3.1	10.2.2	10.3.2	11.4.3	11.4.7	12.2.3	12.3.1	13.2.2	15.1.2
Singer, Donald A., MD Western Pathology Consultants, P.C.	35	13.2.2											
Smith, Vana L., PhD Substance Abuse Program Administrators Association	6	3.6	3.8	9.1.1	9.3.1	9.3.2	11.4.1	11.4.9	15.1.2				
Stenger, Daniel F. and Kathryn M. Sutton Winston & Strawn	13	3.1	19.2.4	19.2.7	19.2.8								
Stewart, William L. Arizona Public Service	29	3.1	3.4	3.5	4.3.1	6.2.2	7.3.4	7.5.2	7.5.4	7.6.9	10.2.1	11.1.1	11.1.8
		11.2.2	11.2.3	11.4.7	15.1.3	15.1.4	15.2.2	17.1.1	19.1.3	19.2.4			
Swartz, Harry M. Maine Yankee Atomic Power Company	14	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	4.2.1	5.2.1	7.1.1	7.1.3
		7.2.1	7.6.8	8.2.6	9.1.1	9.4.1	9.4.2	10.1.1	11.2.2	11.2.5	11.2.10	11.3.1	17.1.1
		18.1.2	18.1.4	18.1.5	18.2.1	19.1.3	19.2.3	19.2.4					
Terry, C. Lance TU Electric	24	4.3.1	5.2.1	7.6.4	9.4.1	10.2.4	14.2.6	15.1.4	15.1.5				
Tipton, Thomas E. Nuclear Energy Institute	5001	3.9.1	3.9.5	3.9.7	17.1.1	17.2.1	17.2.3	17.2.5	17.2.6	17.2.7	17.2.8	17.2.9	17.2.10
		17.2.13											
Toleski, Gary Commonwealth Edison	6010	3.8	3.9.3	7.2.1	7.2.5	7.2.6	9.1.1	9.4.1	9.4.10	10.1.2	10.2.1	10.3.1	11.3.2
		14.1	18.2.4										
Tuckman, M. S. Duke Power Company	32	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	4.2.1	4.3.1	5.2.2	5.2.3
		6.2.2	7.2.1	7.6.4	7.6.8	7.6.11	9.1.1	9.3.1	9.4.1	9.4.4	9.4.6	9.5.3	9.5.4
		9.5.5	9.5.6	10.1.1	10.1.3	10.2.2	10.3.5	11.2.2	11.2.5	14.2.2	14.2.6	15.1.4	17.1.1
		19.2.3											

<i>Name/Organization</i>	<i>Identification #</i>	<i>Section(s) Where Comment(s) Addressed</i>						
Walt, T. D. Carolina Power & Light Company	20	3.1	3.2	3.3	3.4	3.5	3.6	
		3.7	3.8	3.9.3	4.1.2	4.2.1	4.2.6	
		4.2.7	4.2.9	5.2.2	6.1.1	7.1.5	7.2.2	
		7.3.2	7.3.4	7.5.2	7.5.4	7.6.2	7.6.3	
		7.6.4	7.6.7	7.6.8	7.6.9	7.6.10	7.6.11	
		8.2.1	8.2.2	9.1.1	9.3.1	9.3.3	9.4.1	
		9.4.2	9.4.3	9.5.2	9.5.3	9.5.4	9.5.5	
		10.1.1	10.1.3	10.2.1	10.3.1	11.2.1	11.2.5	
		11.3.2	11.4.5	11.4.7	13.2.1	14.2.6	15.1.1	
		15.1.2	15.1.14	16.2.1	17.1.1	17.2.2	17.2.3	
		18.2.1	19.2.3					
Warner, Tara Framatome Technologies	6007	14.2.7						
Willette, Robert E., PhD DuoResearch, Inc.	18	3.1	3.5	9.3.5	9.4.1	9.4.2	9.4.5	
		9.4.6	9.4.7	9.4.8	11.1.3	11.2.6	11.4.6	
		11.4.7	12.2.5	13.1.2	15.1.7	19.2.3		

ATTACHMENT E
FINAL REGULATORY ANALYSIS

**REGULATORY ANALYSIS OF FINAL RULEMAKING
PART 26 - FITNESS-FOR-DUTY PROGRAMS**

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SUMMARY

The NRC has revised the current fitness-for-duty (FFD) regulations for nuclear power reactor personnel contained in 10 CFR Part 26. When the Commission directed the staff to finalize the fitness-for-duty rule in 1989, staff were also instructed to review the need for changes to the rule within 18 months following its implementation date. In March 1991, the staff briefed the Commission on the implementation of the rule and identified areas for change. The changes proposed were based on inspection reports, licensee reports on program performance, licensee reports of significant FFD events, industrywide meetings, initiatives proposed by the Nuclear Management and Resources Council (NUMARC) (now the Nuclear Energy Institute--NEI) and the Substance Abuse and Mental Health Services Administration (SAMHSA) (formerly the National Institute on Drug Abuse [NIDA]), and reviews of technical developments relevant to FFD programs. The final rule package also responds to consideration of public comments on the proposed revisions. This document contains a regulatory analysis of the final rulemaking, hereafter referred to as the rulemaking. It was originally prepared according to guidance set forth in Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 2, 1993, and the Backfit Rule considerations discussed in SECY-93-086. Upon the publishing of Regulatory Analysis Technical Evaluation Handbook, NUREG/BR-0184, January 1997, guidance from that document was used in a later revision of this Regulatory Analysis.

This rulemaking supports the NRC's statutory mission to assure that civilian uses of nuclear materials in the U.S. are conducted in such a manner that ensures public health and safety, environmental protection, and national security. Specifically, the safety concern is that the use of drugs and alcohol and any other causes of impairment or questionable reliability or trustworthiness can increase the probability of safety-significant accidents. The rulemaking is intended to assure the continued effectiveness of the Part 26 regulations in meeting these objectives.

The rulemaking action extends the rule to cover certain classes of FFD program personnel responsible for administering licensee FFD programs; specify return-to-duty testing requirements; clarify medical review requirements following for-cause referrals and other conditions which are not currently addressed in the rule; clarify significant FFD events that must be reported; clarify investigations into unsatisfactory test results; and update drug testing technical standards. A number of improvements made to the rule revise licensee refresher training requirements, FFD record retention requirements, FFD program auditing requirements, and certain technical standards which result in more efficient programs and potential cost savings to licensees.

Several potential cost savings have been identified in the rulemaking. The revisions allow licensees to extend refresher awareness training requirements from 12 to 24 months, accept test results from other licensee programs, eliminate a second breath specimen when the first alcohol breath specimen is negative, reduce the frequency of program performance reports from semi-annually to annually, and reduce the rate

of blind proficiency tests required for analysis. These and other rule changes save licensees an estimated \$27,723,000 annually industrywide.

Since licensee FFD programs are already well established, all costs associated with this rulemaking are expected to be of an incremental nature. The estimated initial, one-time industrywide costs would be \$165,000 for increasing the scope of the rule to include FFD program personnel and for making revisions to policies and procedures to assure compliance with rule changes. The recurring annual cost to implement all other rule changes industrywide would be an estimated \$856,000.

This analysis assumes that the savings and costs associated with the rulemaking would be realized over an estimated average industrywide remaining plant life of twenty years. Assuming a seven percent real discount rate, the present value of the estimated annual industrywide net savings of \$26,867,000 (\$27,723,000 in annually recurring savings minus \$856,000 in annually recurring costs) over twenty years would be \$284,790,000. Taking into account the estimated one-time industrywide costs of \$165,000 that would be incurred in the first year of rule revision implementation, the present value of the industry's net savings over the twenty year period would be approximately \$284,625,000, assuming a seven percent annual discount rate.

ABBREVIATIONS

BAC	Blood Alcohol Content
CFR	Code of Federal Regulations
CY	Calendar year
DOT	Department of Transportation
HHS	Department of Health and Human Services
EAP	Employee Assistance Program
EDO	Executive Director for Operations
FFD	Fitness For Duty
FR	Federal Register
GET	General Employee Training
LOD	Limit of Detection
MRO	Medical Review Officer
NEI	Nuclear Energy Institute
NRC	U.S. Nuclear Regulatory Commission
NUMARC	Nuclear Management and Resources Council
SG	Specific Gravity
SRM	Staff Requirements Memorandum
SAMHSA	Substance Abuse and Mental Health Services Administration
SSNM	Strategic Special Nuclear Materials

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1.0 STATEMENT OF THE PROBLEM

This rulemaking ensures that 10 CFR Part 26 continues to effectively address two related concerns. The safety concern addressed by Part 26 is that evidence has shown that use of alcohol or drugs can impair a worker's motor skills and judgment sufficiently that accidents arising from neglect or human error are more likely to occur. The trustworthiness concern addressed by Part 26 is that licensee employees who knowingly use illegal drugs or abuse legal drugs or alcohol willingly violate the standards set by the licensee as well as society's laws and norms and therefore cannot be trusted to carry out their duties in a safe and secure manner.

While the staff concluded that the rule is fundamentally sound and provides a means for both detecting and deterring abuse of drugs and alcohol, and that no fundamental changes to Part 26 were needed, lessons learned during the past eight years of rule implementation indicated that there are a number of issues that should be addressed. These issues included:

! *Subversion* The exploitation of vulnerabilities in the testing process to avoid detection (testing neither detects nor deters substance abuse if testing is easily subverted).

! *Inefficiencies* The identification of Part 26 requirements that have been shown to have low utility for licensee FFD program effectiveness relative to the resources (time and money) required to meet these requirements.

! *Regulatory friction* NRC licensees are subject to regulation by State and Federal agencies other than the NRC. Additions or changes to the regulatory requirements for drug testing by other agencies, such as Health and Human Services (HHS) and the Department of Transportation (DOT), as well as new legislation (e.g., the Americans with Disabilities Act) have created either incompatibilities or redundancies with the NRC's requirements.

! *Clarifying the original intent of the Commission* In a number of cases there is some confusion regarding the Commission's original intent in Part 26 due to ambiguity in the language of the rule. Resolving these ambiguities would save NRC staff time, increase consistency in the interpretation of the regulation across the industry, and reduce licensee time in interpreting the regulation.

! *Technical developments* Improved drug and alcohol testing practices have been identified that can lead to more effective NRC licensee FFD programs.

This document contains a regulatory analysis of the rulemaking. It was prepared according to guidance in *Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission*, NUREG/BR-0058, Revision 2, 1993, as modified by backfit considerations in the Staff Requirements Memorandum, dated

June 30, 1993, which responds to the Backfit Rule considerations discussed in SECY-93-086, Backfit Considerations.

1.1 BACKGROUND

The NRC issued FFD regulations on June 7, 1989 (54 FR 24468) applicable to licensees authorized to operate a nuclear power reactor and holding a permit to construct or operate a nuclear power plant. Licensee programs implementing the regulations were in place by January 3, 1990. The regulations require affected licensees to implement fitness-for-duty programs to provide reasonable assurance that nuclear power plant personnel are not under the influence of any substance which can adversely affect the performance of their duties. The NRC has since amended 10 CFR Part 26 to require licensees that are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) to institute FFD programs similar to those in the nuclear power industry (58 FR 31467, June 3, 1993). The NRC also amended Part 26 to allow nuclear power reactor licensees and nuclear fuel facility licensees to reduce the random testing rate to an annual rate equal to 50 percent of all persons covered by the FFD regulations (59 FR 502, January 5, 1994). The rule had previously required an annual rate equal to 100 percent.

The NRC is now making further revisions to the current FFD regulations. When the Commission approved the final FFD rule for publication in the *Federal Register*, it recognized that this was a new and evolving discipline and tasked NRC staff to monitor the implementation of the rule, review that experience, and recommend changes that may be needed (SRM of March 22, 1989). When it directed the staff to finalize the FFD rule in 1989, the Commission also instructed the staff to review the need for changes to the rule within 18 months following the rule's implementation date. In March 1991 the staff briefed the Commission on the implementation of the rule and identified areas for possible change. Subsequently, SECY-91-293, *Assessment of Implementation of the Fitness-For-Duty (FFD) Rule and Need for Changes to the Rule*, dated September 17, 1991, provided the Commission with staff recommendations for changes to the rule based on implementation experience.

In briefing the Commission, staff summarized their assessment of the rule's effectiveness as follows: (1) the rule provides an effective means for both detecting and deterring drug abuse; (2) issues raised during implementation of the rule need to be addressed; and (3) the staff have observed noteworthy licensee FFD programs and personnel that have contributed to successful implementation of the rule. Although staff concluded that the need for the rule continued to be valid and that no fundamental changes to the rule were needed, a number of implementation issues were identified that should be addressed. The staff recommended that the Commission address these issues by revising the rule. The staff recognized that, in some areas, courses of action other than rulemaking may sufficiently address the particular issue. The memorandum for James M. Taylor, Executive Director for Operations from Samuel J. Chilk, Secretary, dated November 7, 1991, approved the specific rulemaking activities by the staff except for portions of 4

actions, strongly encouraged the staff to continue to consider further experiences gained from implementation of the rule to identify possible additional areas of the FFD rule where amendments may be needed, and requested that the staff develop amendments to the FFD rule.

SECY-92-308 of September 2, 1992 subsequently identified amendments to the FFD rule that addressed recommended actions by the Commission, recommendations submitted by the Nuclear Management and Resources Council (NUMARC) on April 17, 1991, the additional experience gained since the fall of 1991, and a number of minor changes to the rule needed to ensure consistency or to achieve clarity. SECY-92-308 was withdrawn by the Executive Director's Office (EDO) on February 19, 1993 due to issues with the Backfit Analysis. In response to an SRM dated March 1, 1993 requesting the staff to resubmit the FFD rule changes pending resolution of the backfit issues, the staff resubmitted the rule changes in August 1995. These rule changes included additional recommendations to address issues raised since SECY-92-308 was provided to the Commission. The changes by the staff are based on information obtained from inspection reports, periodic reports by licensees on program performance and reports of significant FFD events, industry-wide meetings, initiatives by NUMARC (now the Nuclear Energy Institute—NEI) and the Substance Abuse and Mental Health Services Administration (SAMHSA) (formerly the National Institute on Drug Abuse [NIDA]), and reviews of technical developments relevant to FFD programs.¹⁰ The NRC published the modifications to the rule for public comment on May 9, 1996 (61 FR 21105). The comment period extended through August 9, 1996, although additional comments were accepted through September 1996, as their acceptance did not impede the comment review process. A total of 36 comment letters were received regarding the rule changes. Comments from a public meeting on the rulemaking and an industry meeting have also been documented. Many of the public comments suggested changes to the Commission's rule changes or recommended new modifications to the current rule. The staff carefully considered and responded to all the public comments in the preparation of the comments and responses NUREG (pending publication). This Regulatory Analysis considers the rule changes published for public comment on May 9, 1996 as modified to accommodate some of the public's recommended rule changes.

The rulemaking seeks to reduce the potential for subversion in drug and alcohol testing programs administered under Part 26 and to improve the effectiveness of the rule in light of program performance during the first eight years of program implementation and in light of technical improvements in drug testing. The rulemaking also seeks to reduce unnecessary burden on licensees. Although overall results indicate that licensee fitness-for-duty programs are working well, the changes are intended to ensure that the general performance objectives expressed in 10 CFR 26.10 are achieved. These general performance objectives are:

¹⁰See Durbin et al. (1991). *Fitness For Duty in the Nuclear Power: A Review of the First Year of Program Performance and an Update of the Technical Issues*. NUREG/CR-5784.

! Provide reasonable assurance that affected workers will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

! Provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of the rulemaking; and

Brief discussions of the five key problems that are addressed by this rulemaking are provided below.

Subversion of the Testing Process

The Problem

Intentional subversion of the drug testing process by those being tested continues to be a major concern of testing programs in industries across the country. Attempts to subvert the testing process are frequently reported in drug testing news letters as the most serious threat to the efficacy of FFD programs being faced by employers today. Testing subversion is a serious problem for at least three primary reasons. First, testing has no deterrent effect on those who have determined it is easy to subvert. It is believed that these people are likely to continue their drug use if they believe they can elude detection through subversion. Second, those who subvert the testing process are most likely to be frequent drug users. These people are precisely those who employers most desire to remove from the workforce. Frequent drug users pose a threat to safety not only through their own actions at work, they are also the people who are most likely to persuade their co-workers to take up drug use. The potential for subversion to discredit drug testing programs is the third reason why subversion is a serious problem for all workplace drug programs. To run efficiently and effectively, drug testing programs need to be accepted as fair and effective by those being tested. Those workers who do not abuse either drugs or alcohol are less likely to accept testing programs if they see their substance abusing co-workers able to escape detection through subversion.

Subversion Techniques

There are three categories of subversion techniques: dilution of urine specimens through consumption of liquids to flush drugs from the system, submission of surrogate specimens, and adulteration of specimens. Drug testing laboratories have reported to the HHS Drug Testing Advisory Board that flushing is the subversion technique most commonly used to avoid detection. It is also the technique recommended by organizations that take an anti-testing stance, such as the National Organization for the Reform of Marijuana Laws (NORML), Byrd Laboratories (Mary Jane's Super Clean 13®), and High Times magazine. Evidence of the prevalence of flushing as a technique is provided by a 1993 study of 10,000 specimens conducted by the HHS National Laboratory Certification Program to evaluate the presence of drugs in specimens which may have been diluted. In that study there were 758 (7.6%) specimens that were

considered dilute, of which 75 (9.9%) were positive after being tested at the testing technique's level of detection (LOD). (Only nine of these 758 specimens were found to be positive when tested at the HHS cutoff levels.) A control group of 758 "normal" specimens produced 21 positives using LOD (using HHS cutoff produced only 2 positives). That is, the dilute specimens were three times more likely than the control samples to test positive at LOD, and four times more likely to test positive at the HHS cutoff levels. The HHS Drug Testing Advisory Board was advised that identifying dilute specimens and subjecting them to LOD testing would double the positive rate.

Dr. Gary Hemphill, of MEDTOX Laboratories, has reported additional evidence of the prevalence of dilution and adulteration. The number of suspect specimens identified by MEDTOX has steadily risen from about 3 percent a few years ago to a current rate of about 5 percent of specimens received for testing. Dr. Hemphill also reported that, although adulteration is a technique frequently detected by the laboratory, flushing is the technique used the most and is successful at producing the most false negative test results. Other laboratories that use a process to determine specimen validity also report 5 percent or more of specimens are suspect.

The submission of surrogate samples is another common technique for avoiding detection. This technique is given occasional attention by the media. Probably the most notorious instance of surrogate sample use was the arrest of an air traffic controller who had 6 surrogate samples kept in the trunk of his car. Although the full extent of NRC licensees' experience with surrogate samples is unknown, two licensed operators, a supervisor and member of an FFD program medical staff, and several workers have been caught submitting surrogate samples.

Intentional adulteration of urine samples is a third general subversion technique. NRC staff have gained evidence of adulteration through voluntary verbal reports from licensees. These reports indicate that specimens containing antifreeze, soap, Mountain Dew, and other adulterants have been detected. Some other adulterants commonly encountered by the testing laboratories and discussed at meetings of the HHS Drug Testing Advisory Board include aspirin to lower rates of absorbency during testing, vitamin B to provide a yellower dilute specimen, and oxidizing agents such as bleach, vinegar, and Visine® eye drops.

Subversion in the Nuclear Power Industry

The prevalence of testing subversion by the nuclear powerplant workforce is unknown. (There are obviously no data on successful acts of subversion.) The staff does, however, have limited data on certain attempted acts of subversion that have been detected during the eight years of FFD program implementation. In November 1991 and May 1992, two operators at the San Onofre facility were detected submitting specimens that were apparently evidence of in vivo dilution (flushing). Similar acts involved a supervisor at the Browns Ferry plant, an employee (who used drugs with supervisors) at Limerick, several

contract workers who submitted surrogate specimens at Washington Nuclear 2, and several other acts (see NUREG/CR 6470 for more detail).

Sections 2.1 and 2.7 of Appendix A to Part 26 permit licensees to analyze suspect specimens for any evidence of adulteration or dilution. The number of licensees implementing this provision is unknown. Furthermore, Section 2.4 (g) informs licensees that the required collection procedures can be considered as only the minimum precautions necessary to ensure that a urine specimen is not adulterated or diluted. The number of licensees that currently take precautions in addition to the minimum is also unknown. What is known is that during a telephone conference call sponsored by Bensinger and Dupont (about one-third of licensees participated), 3 licensees stated that their efforts to identify suspect specimens had produced a dramatic increase in the number of workers being identified as substance abusers. San Onofre has reported that 55 percent of its positives are from dilute specimens. In 1993, San Onofre reported 71 positives from a total of 7,458 tests or a positive rate of 0.95 percent, a rate substantially above the industry average of 0.62 percent. If San Onofre had not taken special measures, FFD staff report that only 32 positives would have been detected.

By implementing the rule revisions designed to counteract subversion, licensees would make the FFD programs more effective in identifying frequent users of drugs, the persons most likely to be subverting the testing process and the persons most likely to endanger public health and safety. The studies conducted by or for HHS indicate that implementation of these revisions could conceivably double the number of substance abusers currently being identified. The data reported by San Onofre confirm this possibility.

Current FFD Program Practices

Incidents of subversion in the nuclear industry and elsewhere have been linked to current FFD program procedures and processes that allow personnel time or opportunity to flush their systems and/or to obtain surrogate samples or other subversion materials, and to the lack of processes to detect adulterated, diluted, or surrogate samples. Inspections and surveys indicate that some licensees are keeping workers on the job and testing them only at the end of a shift even though the workers have been notified that they are to be tested hours before. In addition, some licensees permit delaying tactics that result in lengthy periods between notification and testing.

This information, plus considerable additional evidence gained from the meetings and conversations with licensee FFD staff and licensee reports (e.g., NUREG/CR 5758, Vol. 5, Sec 6.9) indicates that subversion of testing continues to be a problem that there is a compelling need to address.

Staff Recommendations to Combat Subversion

The NRC staff is recommended various rule revisions intended to minimize subversion of the drug testing process. While all of these recommended revisions are fully described later in this Regulatory Analysis, some of the revisions, due to their importance in insuring the integrity and effectiveness of FFD programs, are briefly described here.

The staff recommended that there be a limit set on the allowable interval between the notification of the person that he or she has been selected for testing and the actual collection of the specimen. This revision is intended to eliminate practices by some licensees that permit delaying tactics that enable workers to flush themselves of drugs, metabolize alcohol below detectable levels, and obtain materials that might subvert the test results (e.g., retrieval of adulterants or surrogate samples kept in a desk, locker, or vehicle).

As demonstrated by the following industry experience, this revision is expected to significantly reduce the incidence of subversion. In investigating the reasons why two adjacent sites, drawing their workforce from the same geographic area, had significantly different positive rates for random tests, NRC staff determined that different time intervals between notification and collection was the cause. The licensee with the low rate had a two-hour notification policy not vigorously enforced; the licensee with the higher positive rate had a 15-minute notification policy which it aggressively enforced.¹¹ Subsequent to the inspection, the licensee revised its notification procedure to require the selected person to immediately report for testing; the supervisor timed notification with availability and kept the FFD staff informed. Thereafter, this licensee's positive random testing rate exceeded the industry average.

As other evidence of the need to keep the notification time to a minimum, a DOT study showed an increase in the positive rate when there was little or no prior warning of specimen collection. Whereas normal random testing rates for motor carrier personnel were positive at a 2.5 percent rate, unannounced roadside stops produced positives at a 4.8 percent positive rate. In response to that experience, the DOT revised its rule to require the person to immediately proceed to be tested upon notification. Implementing this proposed action would require licensees to make only minor procedural changes and would not impose any new costs.

The staff also proposed to require the use of a narrower temperature band for measuring the temperature of urine specimens when they are submitted by those being tested. This revision makes it

¹¹In August 1992, IP-3 mishandled the return to duty of a licensed operator (RI reactive inspection 50-285/92-24). In preparing for that inspection, it was noted that in CY 91, IP-3 had no positive results out of 994 random tests, whereas IP-2 had 20 positive results out of 2,002 random tests, a positive rate of 1.00 percent (industry average was 0.33% positive).

more difficult to submit a surrogate specimen. Person and Ehrenkranz¹² reported that the HHS temperature standards may not permit detection of many surrogate samples. A broad temperature range, such as used by HHS, may be necessary if measurement techniques are relatively imprecise and have large margins of error or if collection techniques allow an appreciable interval between voiding and measuring temperature. Temperature measurement with precise instruments and efficient collection procedures can support the use of a narrower temperature band. This proposed requirement is consistent with San Onofre's long-standing practice and practices being adopted by a few other licensees, which have produced good results.

The staff also recommended that licensees should be required to determine specimen validity. Furthermore, since not all dilute specimens are the result of dilution/flushing, the staff recommended that the laboratories test specimens of questionable validity more rigorously than the higher NRC cutoff levels. The likelihood of incorrect determinations of diluting/flushing would be minimized with complete information about the condition of specimens. This also better protects workers' rights by ensuring a correct determination. This revision also minimizes the need to recollect and retest specimens or, in some cases, to collect the next specimen under observation as currently required.

The staff also recommended that licensees that conduct on-site screening tests determine specimen quality to avoid disposal of specimens that would have been determined of questionable validity or invalid by the laboratory. This assumes that all specimens of questionable validity are subject to rigorous analysis at the HHS-certified laboratory.

The staff also proposed that partial specimens from a single donor are to be sent to the HHS-certified laboratory as separate specimens rather than combined, as is the current practice. Keeping the specimens separate would ensure the integrity of the second specimen if the first specimen is suspected of being adulterated or diluted. In addition, keeping the specimens separate decreases the possibility of contamination or error and would prevent the concentration of any metabolites in the first specimen from being diluted by the subsequent specimens, which the donor may produce after having been given liquids to drink.

Inefficiencies

Assessment of the lessons learned from the first eight years of rule implementation identified a substantial number of regulatory requirements that may no longer be necessary. This provides the opportunity to reduce regulatory burden without adversely affecting public health and safety. Examples of key areas where program efficiency could be improved include permitting acceptance of generic portions of

¹²Joel Ehrenkranz, M.D. is Scientific Director for Franklin Diagnostics and an Assistant Professor of Medicine at Columbia University College of Physicians and Surgeons. Dr. Nils Person is a pathologist.

training provided by another licensee, providing more flexibility in pre-access testing, reducing the frequency of program performance reports, changing annual audit frequency to performance-based audit standards, and eliminating the second breath specimen when the first test indicates no alcohol violation. Included in this area are changes addressing Regulatory Review Group Items 18 (audit frequency) and 19 (annual submittal of data) and a petition for rulemaking (PRM-26-1) pertaining to the audit frequency. Reductions in regulatory burden are also in keeping with the National Performance Review.

Regulatory Friction

The requirement having the greatest impact on the NRC's FFD rule is the Department of Health and Human Services' (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (53 FR 11970, April 11, 1988, as amended [59 FR 29907, June 9, 1994]). The Mandatory Guidelines establish scientific and technical guidelines for Federal drug testing programs and standards for certification of laboratories engaged in urine drug testing for Federal agencies. These HHS Mandatory Guidelines apply to the testing conducted in workplaces across the Federal government.

The HHS Mandatory Guidelines are intended to govern programs whose purpose is to reduce the incidence of illegal drug use--these are generally referred to as "demand reduction" programs. The NRC program, on the other hand, is intended more to achieve a safety goal than to reduce the demand for drugs. The Commission has always taken a "zero tolerance" approach to drug and alcohol abuse among nuclear power plant workers. That is, rather than striving simply to reduce demand for drugs among nuclear power industry workers, the NRC fitness-for-duty program's goal is to ensure that licensed activities are not adversely impacted by drugs and alcohol. This is consistent with legal and institutional efforts to achieve a safe work environment in many industries across the nation. Because of the nuclear power industry's responsibilities for public health and safety, the NRC has designed its fitness-for-duty program to detect and remove from protected areas those relatively few nuclear power plant employees who abuse drugs and alcohol. The need to go beyond demand reduction and create a program having a goal of detection and removal has caused the Commission to require somewhat more stringent standards for certain program elements than those provided by the HHS Mandatory Guidelines.

The NRC has stated unequivocally on a number of occasions that the HHS Mandatory Guidelines should provide only minimum standards for the nuclear power industry's fitness-for-duty programs. A Staff Requirements Memorandum dated July 18, 1988 notes that the Commission approved the then proposed fitness-for-duty rule with the expectation that the HHS random drug testing standards should be considered as minimum standards for testing in the nuclear power industry (SRM in response to SECY-88-129, July 18, 1988). In its subsequent notice of proposed rulemaking, the NRC stated that "It should be clearly understood the Commission regards the HHS Mandatory Guidelines as minimum standards. Licensees, at their discretion, may implement programs with more stringent standards (e.g., lower cutoff levels)" (53 FR 36812, September 22, 1988). The NRC reiterated this idea when responding to public comments on the

proposed rule. Several commenters had urged the Commission to adopt the HHS Mandatory Guidelines as minimum standards for chemical testing. The NRC agreed with this recommendation and noted that it had decided to develop its own guidelines for chemical testing due to concerns with the application of the HHS Mandatory Guidelines to the nuclear power industry (NUREG-1354, p. 10-2).

Although the basic purpose of the HHS Mandatory Guidelines differs somewhat from the stringent aims of Part 26, the NRC rule does incorporate much of the HHS Mandatory Guidelines. On June 9, 1994, HHS adopted revisions to its Guidelines (59 FR 29907). Several of the revisions in this rulemaking make Part 26 consistent with the newly revised HHS Mandatory Guidelines.

A substantial number of other legal and regulatory changes have occurred since the original publication of Part 26. For example, significant increases in the requirements for drug and alcohol testing have resulted from the requirements developed for such testing by the operating administrations of the DOT (e.g., the Federal Aviation Administration--FAA--and the Federal Railroad Administration--FRA) and by other federal and state agencies. These changes have had an impact on licensees covered by Part 26 and some of their employees and contractors because people covered by the NRC's rule may also now be covered by other regulations. Under the current NRC FFD rule, this dual coverage results in duplicate testing of people for the same purpose under different regulatory programs. Other changes since the publication of Part 26 include the Family Medical Leave Act, the Clinical Laboratory Improvement Act, and the Fair Credit Reporting Act, and the implementation of the requirements of the Americans with Disabilities Act (ADA).

Another problem faced by licensees with regard to drug and alcohol testing programs is that these programs must be defended when challenged in court. In its proposed rulemaking of 1988, the Commission recognized that it could choose to incorporate significant flexibility into the rule. Such flexibility would enable licensees to decide on a case-by-case basis what actions to take when, for example, determining appropriate sanctions for fitness-for-duty policy violations. The Commission recognized, however, that substantial flexibility could result in serious inconsistencies among licensees in the sanctions imposed for the same types of violations. These inconsistencies would, in turn, leave fitness-for-duty programs vulnerable to legal challenges. The Commission, therefore, decided to create a rule with sufficient specificity and prescriptiveness such that licensees could defend their fitness-for-duty activities against legal challenges (53 FR 36814, September 22, 1988). Therefore, the NRC believes that when needed improvements to the program are identified they should generally be incorporated in a regulation rather than left to industry for implementation. This approach has led to many of the adopted rule revisions.

Clarifying Original Intent of the Commission

During the first eight years of Part 26 implementation, licensees have found a number of rule requirements to be ambiguous. These sections have, therefore, been subject to multiple interpretations across the industry. These ambiguities have been costly to licensees and NRC staff as they have required a substantial number of discussions involving licensee FFD staff, NRC inspectors, and the NRC headquarters staff tasked with the implementation of the regulation. While these discussions have tended to clarify these areas, several Part 26 sections have been revised to eliminate these areas of ambiguity and thus help to assure that the rule is uniformly implemented, inspected, and enforced. One rule revision, for example, makes it clear that the right to appeal FFD drug test determinations covers all categories of workers. Currently applicants for unescorted access are not always granted (or informed of) the right to appeal a positive test result. Since the result of a positive test result deemed to be in violation of the NRC's FFD regulation may have long-term employment consequences for applicants, this clarification has important implications for the protection of their rights. The NRC believes that applicants' rights should be protected consistently throughout the industry.

There are also a number of revisions that improve the clarity of the language of the rule. For example, several terms regarding the testing process and testing results are used inconsistently. This has led to ambiguity in the interpretation of requirements.

Technical Developments

Improvements in drug and alcohol testing practices, based on research findings and the development of new technology, provided the opportunity to increase the effectiveness of Part 26 or to reduce regulatory burden on licensees. Examples of problems identified from ongoing technical research include recognition of the potential for deterioration of specimens stored at high temperatures, evidence that blind performance test specimens are not always accurate (the result of poor quality control practices), and identification of new techniques for subverting the testing process.

1.2 BACKFIT RULE CONSIDERATIONS

The NRC has prepared a detailed analysis of the backfitting applications of each of the changes, which may be found in, "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26)," which is available for inspection and copying for a fee at the NRC Public Document Room. The NRC has carefully considered the backfit issues and has concluded that the revisions being made to 10 CFR Part 26 by this current rulemaking fit into at least one of the following classifications and should be adopted.

1) Clarifications. Several revisions clarify current requirements to assure consistent understanding and implementation of the Commission's original intent for these requirements. Without changing the

underlying requirements stated in these sections, these revisions remove the ambiguities that produced the licensee's uncertainty. The backfit rule does not apply to revisions that leave current requirements unchanged, as these clarifying revisions do.

2) Administrative matters. A few revisions make minor administrative changes, such as correction of typographic errors, correction of inconsistencies, relocating requirements from one section to another, and combining existing requirements into a single section. Administrative matters are not subject to Backfit Rule requirements.

3) Permissive relaxations. Several revisions permit, but not require, relaxations of current requirements (i.e., licensees are free to either comply with current requirements or adopt the relaxed requirements as an alternative). The backfit rule does not apply to rule revisions that provide permissive relaxations of current requirements.

4) Information collection and reporting requirements. A few revisions modify information collection and reporting requirements, which are not considered to be backfits, as set forth in the Committee to Review Generic Requirements (CRGR) charter.

5) Compliance exceptions. Several revisions are necessary to bring licensees into compliance with existing Commission requirements or the Commission's clearly stated intent in promulgating the requirement. In addition, some of the revisions modify current requirements where there is evidence that the current version of the standard is not achieving the purpose that the Commission had when it originally promulgated the rule. These revisions are exceptions to the backfit rule, as specified in 10 CFR 50.109(a)(4)(i).

6) Worthwhile changes to be adopted as Backfit Rule Exceptions. Some of the revisions are recommended for consideration for adoption as an exception to the backfit rule because they are worthwhile changes. The Commission indicated in a Staff Requirements Memorandum (SRM) dated June 30, 1993, (SECY-93-086) that it would consider worthwhile changes on a case-by-case basis as an exception to the "substantial increase" in safety standard, as long as they have been subject to public notice and comment, as these revisions have.

2.0 IDENTIFICATION AND PRELIMINARY ANALYSIS OF ALTERNATIVE APPROACHES

This section discusses the reasonable alternatives considered for meeting the regulatory objectives identified in Section 1.0. Four alternatives were considered:

! Take no action.

! Revise 10 CFR Part 26.

-Comprehensive revision.

-Combine rule revisions and other regulatory and licensee action.

! Address problems through other regulatory means without revising 10 CFR Part 26.

! Licensees take responsibility for resolving problems.

2.1 TAKE NO ACTION

One alternative to the rule changes would be to take no action. Taking no action would allow current practices to continue, or require that certain outstanding FFD issues continue to be addressed on a case-by-case basis. Taking no action allows licensees flexibility in determining the courses of action when they are not constrained by other agencies, legal requirements, or labor negotiations. However, taking no action would disregard the staff and industry recommendations regarding areas for improvement and would continue to impose avoidable costs on licensees. Taking no action at this time would negate the positive impact on the effectiveness of the rule the changes would bring.

Advantages:

! The NRC and licensees would not have to implement changes identified to improve the effectiveness and efficiency of the rule.

Disadvantages:

! The problems identified will not be resolved and the cost savings to utilities will not be realized.

2.2 REVISE 10 CFR PART 26

This option provides the opportunity to resolve some or all of the problems identified. Within this alternative are two options:

! Revise the regulation to comprehensively address the problems identified.

! Use revisions to the regulation to address only those problems that cannot be addressed by other means (e.g., a regulatory guide, licensee meetings).

2.2.1 Comprehensive Rule Revision

A comprehensive rulemaking would provide a means of addressing the problems identified. Measures for preventing subversion would be consistently implemented by all licensees; reductions in regulatory burden can be made; adjustments and changes to regulatory positions and legal actions by other government agencies can be addressed; language can be clarified; and changes to take advantage of technical development can be incorporated.

Advantages:

! Requirements for NRC licensee FFD programs are all addressed in the same document.

! Regulatory change assures consistency across programs and provides opportunities for cost savings (e.g., allowing generic training to be accepted across licensees) that would not be available with more informal approaches.

! Inspection guidance is clear.

! Interested parties are informed about and provided the opportunity to comment on all changes, in one place.

! Many problems, such as responding to regulatory and legal issues, can best be addressed via a formal rule revision.

Disadvantages:

- ! The incorporation of an appreciable number of changes makes the rule package unwieldy.
- ! Some matters may be best left to the initiative of licensees and may not require regulatory change.

2.2.2 Combine Rule Revision with Other Regulatory and Licensee Actions

While some problems, such as those created by regulatory and legal action, can best be addressed by rule revision, other problems, such as some of the ambiguities in the language of the regulation, could be resolved via other means, such as a regulatory guide or licensee meetings.

Advantages:

- ! Addresses all problems in some manner.
- ! Reduces changes to the regulation.
- ! Provides more informal and potentially flexible resolutions to some problems.

Disadvantages:

- ! No permanent solution to many problems.
- ! Preparing multiple responses would be more time-consuming and costly.
- ! Continued inconsistency in program implementation, inspection and enforcement. Currently some licensees have aggressive programs while others do the minimum they interpret is required by the rule. Areas where changes are not included in the regulation are expected to continue to experience these discrepancies.
- ! Licensees would not have a comprehensive source of guidance.
- ! Interpretations of ambiguous language would still be required with continued program differences, and difficulties in maintaining consistency in the inspection and enforcement programs.
- ! Process to promulgate guidance is equivalent to rulemaking.
- ! Changes are interrelated, and it may be inappropriate to have some required and some suggested.

2.3 ADDRESS PROBLEMS THROUGH REGULATORY MEANS OTHER THAN REVISIONS TO PART 26

Advantages:

! Would allow licensees more flexibility.

Disadvantages:

! Would not be able to address all of the problems identified, as direct regulatory changes are required to address regulatory friction.

! No permanent solution to many problems.

! Preparing multiple responses would be more time-consuming and costly.

! Continued inconsistency in program implementation, inspection and enforcement. Currently some licensees have aggressive programs while others do the minimum they interpret is required by the rule. Areas where changes are not included in the regulation are expected to continue to experience these discrepancies.

! Licensees would not have a comprehensive source of guidance.

! Interpretations of ambiguous language would still be required with continued program differences, and difficulties in maintaining consistency in the inspection and enforcement programs.

! Process to promulgate guidance is equivalent to rulemaking.

2.4 LEAVE RESOLUTION OF PROBLEMS TO THE LICENSEES

Advantages:

! No regulatory action by NRC required.

Disadvantages:

! Would not be able to address all of the problems identified, as direct regulatory changes are required to address regulatory friction.

! No permanent solution to many problems.

! Preparing multiple responses would be more time-consuming and costly.

! Continued inconsistency in program implementation, inspection and enforcement. Currently some licensees have aggressive programs while others do the minimum they interpret is required by the rule. Areas where changes are not included in the regulation are expected to continue to experience these discrepancies.

! Licensees would not have a comprehensive source of guidance.

! Interpretations of ambiguous language would still be required with continued program differences, and difficulties in maintaining consistency in the inspection and enforcement programs.

3.0 CONSEQUENCES

This section discusses the benefits, cost savings, and costs that may result from the implementation of the rulemaking.

3.1 ESTIMATION OF SAFETY-RELATED BENEFITS

The benefits of the rulemaking were analyzed in terms of the general performance objectives stated in Section 1.0, namely, to assure that personnel with unescorted access to the protected areas of a nuclear power plant facility are free from the adverse effects of drugs and alcohol, to assure that personnel are fit to perform their duties free from the effects of other causes of impairment, and to assure that personnel are trustworthy. These benefits are not readily quantifiable. Qualitative benefits accrue mainly from increased safety by ensuring that workers are fit for duty.¹³ The benefits from the rulemaking would accrue from the increased effectiveness of the FFD rule in addressing the performance objectives originally set forth in the rule.

Drug and alcohol use and abuse can impair job performance. This impairment is not only a significant threat to the safety of workers themselves, but may also endanger public health and safety. Drug use or alcohol consumption on the job can adversely affect behavior and diminish both physical and cognitive abilities. The effects of withdrawal, hangover, and long-term chronic abuse from off-duty drug and alcohol use can also affect job performance. Drug and alcohol abuse can have a significant impact on safety-related jobs. Drug use remains prevalent in American society, and is an ongoing occupational and safety concern in American industry.¹⁴ Drug or alcohol abuse by nuclear industry personnel indicates a lack of reliability and trustworthiness and remains a legitimate safety concern for the NRC.¹⁵

The NRC's Backfit Analysis prepared in 1989 in conjunction with promulgation of the Part 26 FFD rule concluded that drug abuse significantly increases the risk of accidents as a result of neglect or human error.¹⁶ Although the reduction in risk due to the implementation of FFD programs was not quantified, the

¹³For discussions of safety-related fitness-for-duty concerns, see NUREG/CR-5227 (Barnes et al., 1988), NUREG/CR-5227 Supplement 1 (Moore et al., 1989), and NUREG/CR-5784 (Durbin et al., 1991), and NUREG/CR 6470, Durbin, N. & Grant, T., 1996).

¹⁴NUREG/CR-5784 and NUREG/CR-6470, Ch. 6.

¹⁵54 FR 24470, June 7, 1989. Fitness-For-Duty Programs; Final Rule and Statement of Policy. Federal Register.

¹⁶Backfit Analysis, p. 6.

1989 Backfit Analysis stated that drug and alcohol testing as part of a comprehensive FFD program can significantly increase the assurance that employees will be fit for duty. The NRC concluded that FFD program implementation costs were justified by increasing the assurance of public health and safety.

During 1990, the first calendar year of FFD program implementation, 0.87 percent of tests administered under 10 CFR 26 requirements were confirmed as positive for the presence of illegal drugs or the abuse of alcohol. In 1993, the fourth year of program implementation, 0.62 percent of tests administered under 10 CFR 26 requirements were confirmed as positive for the presence of illegal drugs or the abuse of alcohol. In 1995, the confirmed positive test rate was .98 percent. The breakdown by test category is shown in Table 1 (1990), Table 2 (1993), and Table 3 (1995). The 1995 confirmed positive test rate should not be directly compared to the rates from previous years because of several changes that had occurred during the intervening years, the most significant being 58 FR 31467, which reduced the random testing rate to an annual rate equal to 50 percent of all persons covered by the FFD regulation, effective January, 1994. A substantial portion of the increase in the positive test rate between 1993 and 1995 can be explained by the reduced random testing rate requirement.¹⁷ Other factors, such as the increase in the number of reporting units using lower screening cutoff levels for THC and licensees' greater stridency in attempting to prevent subversion, also contribute to the increase in the positive rate. While these factors provide some explanation for the increase in the confirmed positive test rate that has occurred since 1993, the NRC believes that any drug use in the nuclear industry warrants continuing prevention efforts and proactive intervention to ensure public safety.

In addition, assuring that workers were not impaired by drugs or alcohol was found to decrease the probability of human error and would reduce the risk of accidental radiological exposure to plant personnel. This reasoning is applicable to the current rulemaking in that changes to improve the effectiveness of the rule should further decrease the risk of accidental radiological exposure as a result of human error caused by a fitness-for-duty problem. Although the probability of a significant accidental radiological release due to drug abuse may be low, the consequences of such a release could be great. Furthermore, any radiological accident attributed to drug or alcohol use could undermine public confidence in nuclear industry safety. The relatively low positive test rates reported in NUREG/CR 5758 indicate that drug abuse among nuclear power plant personnel may not be as great as in the national work force. Although the positive test rates do not reveal the actual prevalence of drug abuse and may possibly present a low estimate of drug abuse within the industry, they indicate that through the FFD program there is a continuous detection of previously undetected drug use. The positive test results indicate that there continues to be a number of nuclear power plant personnel with a drug abuse problem; therefore, efforts to improve the effectiveness of the current Part 26 requirements are warranted.

¹⁷ Silbernagel et al. (1995). Fitness For Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports CY 1993. NUREG/CR-5758, vol 6, page 21.

Table 1. FFD Test Results (CY 1990)

Test Category	Number of Tests	Number of Positive Tests	Percent Positive
Pre-employment/ Pre-access	122,491	1,548	1.26%
Random	148,743	550	0.37%
For-Cause/ Post Accident	732	214	29.23%
Follow-Up	2,633	65	2.47%
TOTAL	274,599	2,377	0.87%

Source: Durbin et al. (1991). Fitness For Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports CY 1990. NUREG/CR-5758, Appendix A, page A-3.

Table 2. FFD Test Results (CY 1993)

Test Category	Number of Tests	Number of Positive Tests	Percent Positive
Pre-employment/ Pre-access	91,471	952	1.04%
Random	146,605	341	0.23%
For-Cause/ Post Accident	751	163	21.70%
Follow-Up	4,139	56	1.35%
TOTAL	242,966	1,512	0.62%

Source: Westra et al. (1994). Fitness For Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports CY 1993. NUREG/CR-5758, vol. 4, page 5.

Table 3. FFD Test Results (CY 1995)

Test Category	Number of Tests	Number of Positive Tests	Percent Positive
Pre-employment/ Pre-access	79,305	1,122	1.41%
Random	66,791	180	0.27%
For-Cause/ Post Accident	763	139	18.22%
Follow-Up	3,262	35	1.07%
TOTAL	150,121	1,476	0.98%

Source: Silbernagel et al. (1996). Fitness For Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports CY 1995. NUREG/CR-5758, vol. 6, page 3.

3.2 ESTIMATION OF ADDITIONAL SECONDARY IMPACTS

Secondary impacts are also likely to accrue to affected licensees from improving the effectiveness of the rule, including enhanced workforce productivity, reduced absenteeism, lower medical and insurance costs, and less plant downtime. The effects of human-related errors caused by fitness-for-duty problems can have direct and indirect effects on overall plant operating costs. For instance, a 24-hour outage caused by a fitness-for-duty related error may result in a direct revenue loss of several hundred thousand to over a million dollars. Furthermore, the long-term effects of fitness-for-duty problems arising from increased absenteeism, lower productivity on the job, and increased use of medical benefits can also result in higher costs to the licensee.¹⁸ These secondary impacts will offset to some extent the costs associated with implementation of these rule revisions, but are not taken into account in the decision rationale for the rulemaking discussed in Section 4. Furthermore, substance abuse is a significant drain on the national economy. Improved FFD programs will make a contribution, albeit small, toward improving the national economy.

3.3 ESTIMATION OF MONETARY BENEFITS, COST SAVINGS, AND COSTS

As discussed in Section 1, this rulemaking is being conducted to ensure that Part 26 continues to effectively address two related concerns. The safety concern addressed by 10 CFR Part 26 is that evidence has shown that use of alcohol or drugs can impair a worker's motor skills and judgment sufficiently that accidents arising from neglect or human error are more likely to occur. The trustworthiness concern addressed by 10 CFR Part 26 is that licensee employees who knowingly use illegal drugs or abuse legal drugs or alcohol willingly violate the standards set by the licensee as well as society's laws and norms and therefore cannot be trusted to carry out their duties in a safe and secure manner. Specific changes to the rule analyzed below address:

- ! Concerns related to subversion,
- ! Inefficiencies that place an undue burden on licensees,
- ! Regulatory friction between NRC requirements and other federal agency drug-testing programs,

¹⁸See, for instance, Crouch, D. J., et al. (1989). A Critical Evaluation of the Utah Power and Light Company's Substance Abuse Management Program: Absenteeism, Accidents and Costs. In: S. W. Gust, & J. M. Walsh (Eds.), Drugs in the Workplace: Research and Evaluation Data. NIDA Research Monograph 91. Washington, D.C.: U.S. Government Printing Office, pp. 169-193.

- ! The need to clarify the original intent of the rule, and
- ! Evolving technical developments that should be reflected in the rule requirements.

Where appropriate, estimated cost savings and costs are compared to the calendar year (CY) 1990 costs incurred by nuclear power reactor licensees as estimated by NUMARC. These costs were collected by NUMARC from cost data submitted to it by utilities operating all 116 units that were subject to the Part 26 rule requirements at that time.¹⁹ For this analysis NUMARC cost data are inflated to 1995 dollars for comparison.²⁰ In addition, this analysis draws upon the most current compilation of industry program performance industry data as reported in Silbernagel et al. (1996), Fitness For Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports CY 1995. NUREG/CR-5758, vol. 6.

Calculating discrete and industrywide costs involved two units of analysis: costs were either calculated by FFD program or by reactor unit/nuclear fuel facility. Currently, there are a total of 72 nuclear power licensee FFD programs or sites covering 110 operating reactors (some programs provide FFD information for several reactor units, and several of the 48 nuclear utilities have more than one FFD program). Another 873 people employed by two nuclear fuel facilities are also covered by the rule (600 employees at one facility and 273 at the second).²¹ Therefore, for purposes of this analysis, there are a total of 74 licensee programs and a total of 112 reactors and nuclear fuel facilities affected by the rule changes. Cost-related information in the following sections is provided either for operating reactor/nuclear fuel facility unit or at the FFD program level, depending on where cost impacts are incurred, i.e. programmatic costs or unit-specific costs. For instance, it is assumed that FFD program personnel costs would be incurred at the program level rather than at the reactor unit level. In other cases, however, it is more useful to calculate costs at the reactor unit level, for instance, FFD supervisory training costs per person.

As reported in NUREG CR-5758, Volume 6, Appendix A, 72 licensee programs reported an average program testing population of 1,023 employees and 487 contractors, for a total average population

¹⁹NUMARC cost data are summarized in a September 20, 1991 letter from Thomas E. Tipton, NUMARC, to Brian K. Grimes, NRC.

²⁰This estimation of monetary benefits, cost savings, and costs was originally prepared in 1995. The staff has chosen not to inflate the benefit and cost figures to 1998 dollars due to the significant effort and expense it would take to convert the data in the original analysis, particularly in light of the relatively small difference there is between 1995 and 1998 dollars.

²¹SSNM transporters who are subject to either the U.S. Department of Transportation or U.S. Department of Energy drug and alcohol fitness programs that require random testing for drugs and alcohol are not subject to Part 26 requirements. The proposed amendments, will, therefore, have no effect on these employees.

size of 1,510. The addition of a total of 873 employees at the two nuclear fuel facilities covered by the rule results in a total of 109,593 personnel covered by 74 programs under 10 CFR Part 26, for an average of 1,481 individuals per program. The 112 reactor/nuclear-fuel-facility units have an average population of 979 individuals covered at each unit (109,593/112). Therefore, the following estimates are used throughout the analysis:

- ! Each of 74 FFD programs has an average testing population of 1,481 people.
- ! Each of 112 units covered by FFD programs has an average testing population of 979.

Table 4. Population Estimates Used in the Analysis

	Reactor Licensee	Fuel Facility	Total
Number of Testing Programs	72	2	74
Number of Units*	110	2	112
Average Population per Program	1,510	873**	1,481
Average Population per Unit	988	873**	979

*Reactor or fuel facilities.

**Total number of employees at the two fuel facilities (600 + 273).

3.3.1 Current FFD Programs of Affected Licensees

All licensees affected by the rulemaking currently have established FFD programs. All costs associated with this rulemaking are therefore expected to be of an incremental nature. Furthermore, the rulemaking identified a number of potential cost savings to licensees, further offsetting the incremental costs associated with this action.

3.3.2 Estimation of Benefits, Cost Savings, and Costs by Rule Section

The following sections address the estimated potential benefits, cost savings, and costs that the rulemaking creates. Although there are many discrete revisions, only those that could have a significant potential benefit, cost savings, or cost impact will be addressed here. All potential benefits, cost savings, and costs are expressed as annual amounts in 1995 dollars. Many of the changes clarify the original intent of the rule, or implementation of the rule change requires only a small change in current FFD operations. In many of these cases staff concluded that there would be no significant cost impacts incurred by licensees.

26.1 Purpose

No changes were made to this section.

26.2 Scope

The Commission's original intent was that FFD program personnel meet the highest standards for honesty and integrity to assure that the program produced valid results and was not being subverted. This was intended to include testing. Although the current rule does not explicitly require testing of FFD personnel, licensees (with very few exceptions) are testing them to meet the requirements of Section 2.3 of Appendix A (to ensure reliability and trustworthiness). So the actual cost impact on licensees will be negligible. The rulemaking amends Section 26.2 (a) to clarify the Commission's original intent that FFD program personnel be included within the rule's scope. Specifically this section is revised to explicitly include FFD program personnel with the following duties:

- ! Personnel who can link test results with the person who was tested prior to determination of a FFD policy violation (e.g., the Medical Review Officer (MRO), the FFD program manager, and selected administrative staff),

- ! Personnel who make medical and management determinations of fitness, (e.g., the MRO and FFD program manager).
- ! Personnel making removal and return-to-work decisions (e.g., the MRO, the FFD program manager, and selected administrative staff), or
- ! Personnel involved in the selection and notification of employees for testing and in the collection and on-site testing of specimens.

Although these people normally work outside the protected area, their actions do have an ongoing effect on safety. People who administer testing programs are in a position to permit substance abusers to remain undetected. This could occur inadvertently as a result of impaired behavior because of substance abuse or intentionally because of motives associated with substance abuse (such as empathy or collusion with the abuser). Furthermore, the omission of these individuals from testing and other program requirements tends to undermine the credibility of licensees' FFD programs.

Several reported incidents have confirmed the need to assure that FFD program personnel meet the highest standards of honesty, integrity, reliability, and trustworthiness. For example, one licensee added collection personnel to the testing pool after investigation of an allegation determined that two specimen collectors were substance abusers. In another instance, a contracted MRO not in the testing pool was reported to be an alcoholic and an abuser of prescription drugs. At another licensed facility, an FFD staff member was found to have entered the testing area at night to replace her own specimen that had been collected earlier that day. Another incident involved an FFD staff member who alerted an employee of his impending drug test so that he could leave the site prior to official notification. In still another reported incident, a collection site person falsified testing records to conceal a positive breath analysis for alcohol.

Although there have been relatively few abuses in FFD program administration to date, these incidents raise concerns by licensees and NRC staff regarding the overall integrity of the testing process. The revision to Section 26.2 (a) fulfills the NRC's original objective for this section (which is reflected in most FFD programs) and ensure continued protection of public health and safety.

Several cost impacts were identified for this action. It is assumed that most licensees (72 of 74 sites) currently include all FFD program personnel within the scope of their FFD program as originally intended by the rule. It is also assumed that approximately one half of licensees do not include their contract MRO services in their program. According to data submitted by NUMARC, two to seven positions are required to staff on-site licensee FFD programs, excluding EAP services. Assuming an average FFD program staff of four people who may be eligible for testing, it is estimated that two programs would need to add four people to their testing program and 37 programs would need to add two people (the contract

MRO services) to the testing program. The following cost centers are used to assess the overall costs of the revisions to Section 26.2 (a).²²

Development of Written Policies and Procedures. There should be no significant additional costs associated with developing policies and procedures for testing FFD program personnel since the FFD policies and procedures are already developed. Modifications to the FFD policies and procedures that pertain uniquely to FFD program personnel are expected to be minimal, and are considered a minor revision to current FFD program policies and procedures. Costs associated with modifying FFD policies and procedures are treated separately in the discussion of revisions to Section 26.20.

Initial Awareness Training Program. It is assumed that all licensee FFD program personnel newly included in the scope of the rule will need an initial training course to ensure their understanding of the scope of the FFD program, the consequences of substance abuse, and the availability of assistance through the licensee Employee Assistance Program (EAP). On the basis of generic cost estimates for training provided in NUREG/CR-4627, the estimated training cost per student hour would be \$33.24, exclusive of the student's time away from work.²³ That estimate includes the instructor's time for developing, preparing, delivering, evaluating and revising the course, and the costs of instructional materials and handouts. However, since the training programs and materials have already been developed, and the courses presented periodically, the generic cost does not apply; a more realistic figure would be zero since these few additional persons can be added to existing periodic training sessions. The student's time is valued at \$52.80 per hour.²⁴ As shown in Table 4, this is the average hourly salary paid to various FFD program staff personnel adjusted for fringe benefits and plant management and escalated to 1995 dollars.

It is estimated that the training would be an one-hour course. The initial training cost for programs adding four FFD program personnel would be \$211.20 per program (four people x \$52.80 per person). The initial training cost for programs adding two FFD program personnel would be \$105.60 (two people x \$52.80 per person).

²²Cost centers are the same as those used in the Backfit Analysis for the original FFD rule and correspond to the major rule sections.

²³NUREG/CR-4627, Generic Cost Estimates, Science & Engineering Associates, Inc., S. Cohen and Associates, and MATHTECH, Inc., Abstract 2.2.3, "Industry Costs for Training or Retraining Staff and Writing or Rewriting Training Manuals," Table 4.1. Cost assumes a 1988 average training hour cost of \$25.00/hour, inflated to 1995 costs using the Projections of Gross National Product Price Deflator (PGNPDP), Abstract 6.3, "Time-Related Cost Adjustments," Table 4.3.

²⁴See Table 5, "FFD Program Staff Costs." Cost assumes an average FFD program personnel wage rate of \$52.80 per hour, inflated to 1995 costs using a utility labor annual growth rate in addition to inflation of 0.8 percentage points, and a fringe benefit multiplier of 2.0 (NUREG/CR-4627).

It is estimated that one supervisor (either an MRO, FFD Manager, licensee manager or designate) would participate in an additional four hour supervisory training course. The incremental cost is nominal because the supervisor could attend existing periodic training sessions. The cost of this training would be four hours' training time multiplied by \$70.71 per hour labor cost (estimated for a supervisory position). The supervisory training cost for programs adding four FFD program personnel would be \$282.84 per FFD program (four hours x \$70.71 per hour).

Table 5. FFD Program Staff Costs²⁵

Position Title	Job Duties	Number of Positions	Base Rate/Hour (1988)	Labor Cost/Hour (1995)
Collection Site/Clerical Personnel	iv	2	12.35	33.39
Medical Review Officer	i, ii, iii	1	35.00	94.64
Medical Review Officer Clerical Staff	i, iii	1	12.35	33.39
FFD Manager	i, ii, iii, iv	1	26.15	70.71
FFD Manager Clerical Staff	i, iii, iv	1	12.35	33.39
Licensee Manager or Designate	ii, iii	1	26.15	70.71
			Average Base Rate/Hour:	Average Labor Cost/Hour:
TOTAL		7	\$19.53	\$52.80

Notes:

- i = Personnel who can link test results with the person who was tested, prior to determination of a FFD policy violation
- ii = Personnel who make medical and management determinations of fitness
- iii = Personnel making removal and return-to-work decisions
- iv = Personnel involved in the selection and notification of employees for testing and in the collection of specimens

The original MRO base wage estimate was derived from FFD Rule Backfit Analysis.
 1992 Labor Cost = 1988 Base Rate/Hour adjusted for inflation x 2.0 fringe benefit.

The total initial training cost for FFD program personnel is estimated to be \$494.04 (\$211.20 plus \$282.84) at the two programs that would add four people. In the case of programs adding the MRO services, it is assumed that supervisory oversight is the responsibility of the FFD program manager. Since the FFD program manager will have received supervisory training, no additional supervisory training costs for these people is assumed.

²⁵NUMARC has noted that programs range from two to seven positions (not including EAP personnel). It is assumed that, for purposes of the analysis, four people on average are in FFD programs.

Refresher Awareness Training. FFD program personnel subject to the rule will be required to attend refresher training programs. NRC licensed facilities generally conduct General Employee Training (GET) programs covering safety and security issues. Refresher training for the FFD program at most sites has been incorporated into the present GET programs. Therefore, no additional refresher training costs are assumed for implementation of the revision to Section 26.2 (a).

Pre-Access and For-Cause Chemical Testing. FFD program personnel included within the scope of the rule as a result of the rule change are required to submit an initial specimen in compliance with Section 26.24 (a) (1) of the rule which requires a test before “assignment to activities within the scope of this Part.” The estimated cost of testing FFD personnel is based on the following assumptions:

- ! It will take an employee one hour to reach the test site, be tested, then return to work.
- ! Since the type of employee (job classification) which will be affected by the rulemaking varies widely, a standard FFD program personnel wage rate of \$52.80 per hour including a fringe benefit multiplier of 2.0 is assumed.
- ! All specimens collected from FFD program personnel will be sent off-site to a HHS laboratory for testing (no on-site testing).
- ! The average cost of chemical testing by a HHS laboratory is \$50.00. This cost includes the specimen collection labor costs, shipping to an off-site laboratory, initial screening and confirmatory testing, if necessary, and reporting of results to the licensee. In 1991 NUMARC estimated the cost of testing to range between \$15 and

\$100 for off-site testing. However, this estimate did not include the cost of specimen collection, which was estimated to range between \$10 and \$115 per specimen.^{26, 27}

The estimated one-time cost for each licensee affected by the rule change would be the cost of the test plus the cost of the employee's time away from his or her normal duties.²⁸ Substituting the assumed values yields a cost estimate of \$102.80 per test (\$50.00 per test plus [1.0 hours x \$52.80 per hour]). The total estimated one-time cost per licensee adding four FFD program personnel for additional required pre-access testing would be \$411.20 (4 tests x \$102.80 per test). The total estimated one-time cost per licensee adding two FFD program staff for additional required pre-access testing would be \$205.60 (2 tests x \$102.80 per test).

Some costs are also likely to be associated with having personnel who are not FFD coworkers available to collect specimens for pre-access tests. It is estimated that it would take 1 hour specimen collection time per test. Assuming an average specimen collection labor cost of \$33.39 per hour, the total cost of this additional cost per licensee adding four additional people is estimated to be \$133.56 (\$33.39 per hour x four hours). The total cost of adding two additional people would be \$66.78 (\$33.39 per hour x two hours).

Overall the one-time cost of pre-access testing is estimated to be \$544.76 (\$411.20 plus \$133.56) for each licensee adding four people, and \$272.38 (\$205.60 plus \$66.78) for each licensee adding two people.

²⁶Letter to Brian K. Grimes, NRC, from Thomas E. Tipton, NUMARC, September 20, 1991.

²⁷Testing costs are very competitive. Evidence indicates that this competition is driving the costs of testing down, resulting in significant cost variations between licensees, laboratories, and geographic region. Testing costs may also vary because they can be calculated in several ways, making direct cost comparisons and industrywide estimates difficult. For instance, a licensee may use a flat fee contract where a laboratory provides testing services over a certain period regardless of the total number of tests submitted for analysis. A second method of calculating testing costs would be to charge a flat rate per specimen for the initial immunoassay screening, and pro-rate the more expensive costs of GC/MS testing, which may be required for relatively few of the total number of specimens. A third way to charge for laboratory testing is to charge separately for immunoassay screenings and GC/MS confirmatory testing. [For a review of testing methodologies, see NUREG/CR-5227 (1988), and NUREG/CR-5227, Supplement 1 (1989)]. Therefore, a mid-point estimate of \$50 per test is assumed. This estimate does not include the cost of lost work time, and is therefore consistent with estimates of drug test costs made by the U.S. General Accounting Office and the U.S. Department of Defense (Drug Detection Report, August 5, 1992; Drug Detection Report, August 20, 1992).

²⁸Additional costs associated with alcohol testing are expected to be minimal. Licensees already have established procedures and equipment for breath alcohol tests, and additional discrete costs associated with alcohol tests as part of the testing procedure are therefore considered a minimal incremental cost. Personnel being tested have the option to submit a blood specimen to test for the presence of alcohol; this is not likely to be a significant cost since few individuals tested request this procedure.

The estimated cost of for-cause testing for FFD program personnel is based upon data concerning the extent of for-cause referrals in the nuclear power industry during the sixth year of program implementation.²⁹ Although information provided to NRC staff indicates that there were a few for-cause tests of FFD program personnel in the first six years of program implementation, the probability of an FFD program staff person being referred for-cause for whatever reason is very low statistically. In 1995 a total of 763 for-cause tests were reported by licensees, or an average of 10.45 tests for each of the 72 FFD programs (NUREG/CR-5758, vol. 6). Assuming an average FFD program testing population of 1,481 people, the average likelihood of any FFD person being referred for-cause is four FFD staff out of 1,481 people per site population, or approximately 0.3 percent probability of referral (the likelihood would be even less for programs adding two people). Therefore, this requirement is expected to have an insignificant cost impact on licensees.

Random Testing. The current rule requires each licensee to conduct random testing at an annual rate equal to at least 50 percent of the covered workforce. The estimated cost to include FFD program personnel in the random testing program assumes a cost of \$102.80 per test, including the employee's time away from work. The total estimated recurring annual cost of random testing per FFD program is \$205.60 for programs adding four people (2 tests x \$102.80 per test) and \$102.80 for programs adding two people.

Some costs are likely to be associated with having non-FFD co-workers collect specimens. It is estimated that it will take one hour specimen collection time per test. Assuming an average specimen collection labor cost of \$33.39 per hour, the total cost of this additional cost per site per year is estimated to be \$66.78 for programs adding four FFD personnel (\$33.39 per hour x 2 hours) and \$33.39 for programs adding two people.

Overall, the total annual recurring costs of random chemical testing for FFD program personnel is estimated to be \$272.38 for licensees adding four people (\$205.60 plus \$66.78) and \$136.19 for licensees adding two people (\$102.80 plus \$33.39).

Blind Proficiency Testing. Licensees are required to conduct blind proficiency testing to assure that testing is done properly and the results are accurate. The current number of blind samples submitted for analysis is required to represent approximately 10 percent of all samples submitted for analysis (new programs are required to submit 50 percent in the first quarter of implementation and 10 percent for each subsequent quarter). Overall, it is estimated that the additional testing of FFD program personnel should be an insignificant cost burden (e.g., an estimated 4 FFD program personnel x 50

²⁹Silbernagel, et al. (1996). Fitness for Duty in the Nuclear Industry: Annual Summary of Program Performance Reports CY 1995. NUREG/CR-5758 Vol. 6.

percent random test rate in the first year x ten percent blind proficiency test rate).³⁰ Revisions to Section 2.8 (e) (2) (discussed below) will further reduce the total number of blind proficiency specimens that licensees are required to submit for analysis; this will likely reduce the blind proficiency testing costs for FFD program personnel but is not considered here.

Additional Personnel. Each licensee affected by the revision to Section 26.2 may need additional MRO assistance to objectively review test results independent of conflicting relationships with FFD program personnel. Due to the assumed low prevalence of drug abuse expected to occur among FFD program personnel, this requirement is expected to have no significant cost impact on licensees.

Record and Specimen Storage. Each HHS-certified laboratory includes in its testing charge a fee to store specimens for 1 year. Therefore, no additional record and specimen storage costs would be incurred.

Employee Assistance Programs. Licensees currently have FFD programs in place in accordance with the Part 26 provisions. Staff believes licensees can easily absorb the additional testing of four FFD program personnel into their current EAP programs. On average 1,481 people are covered by the provisions of Part 26 in each licensee's FFD program and therefore these personnel are provided access to EAP services (NUREG/CR-5758, vol. 6). The additional personnel represent a less than one percent increase in the total testing population; consequently, the impact on overall EAP costs is expected to be insignificant, if any.

Section 26.2 (f) is added as a new section to the rule. Persons covered by a program regulated by another Federal agency or State need be covered by only those elements of a licensee's fitness-for-duty program not included in the Federal Agency or State program, as long as all such persons are subject to pre-access, random, and for-cause urine testing for the drugs specified in the HHS Mandatory Guidelines and at

³⁰It is estimated that the cost of blind proficiency testing is \$65 per specimen, including the cost of the specimen preparation, shipment for analysis, analysis, reporting of results, and MRO review. Blind proficiency tests can cost \$30 to \$35 for manufactured specimens, including a master list of what the specimens contain. Other costs associated with blind proficiency testing include the cost of MRO review, decoding the master sheet against the test results reported by the laboratory, and contacting the laboratory when blind proficiency questions arise or errors are found. Alternatively, licensees may prefer to prepare their own spiked samples for off-site screening. The total estimated cost for a blind proficiency testing specimen prepared by the licensee is estimated to be about \$3 per specimen, plus the cost of testing, MRO review, and disposition. Overall, the costs per blind proficiency specimens may be expected to range from \$50 to \$80 when these factors are considered. Therefore, an estimate of \$65 per test is assumed for purposes of this analysis.

mandated cut-off levels; have their breath tested for alcohol, at or below NRC levels; have their urine specimens tested at a laboratory certified by HHS, the College of American Pathologists, or other comparable certification program; have awareness training, and have access to an impartial objective procedure for appealing any findings of a FFD violation. To ensure there is no increased risk to public health and safety, licensees will continue to be responsible for ensuring these people are fit for duty through behavioral observation, for immediately removing unfit people from Part 26 duties, and for-cause testing. In addition, Section 26.2 (f) stipulates that provisions must be in place through which the testing agency or organization will notify licensees granting unescorted access of any FFD violation. Any differences in specific program requirements, such as the use of different cut-off levels should have no significant effect on the program in meeting the general performance objectives. This revision reduces the burden on individuals covered by duplicate Federal and State programs.

This rule revision represents a potential cost savings to licensees and to the agencies that cover these people in the scope of their requirements. The rule change eliminates duplicate testing for people covered by both DOT and NRC rules (estimated to range from 40-75 people per licensee). Therefore, it is assumed that an average of 50 people per FFD program would not be subject to duplicate random testing each year. Based on the 50-person assumption, it is also assumed that in any given year there will be four people seeking unescorted access who, except for this rule change, would join this group of 50 people subject to duplicate requirements. The estimated savings would be the cost of the employee's time away from his or her normal duties,³¹ the cost of testing, and the cost of suitable inquiries. The estimated cost of testing is \$94.78 per test (\$50.00 for the test and \$44.78 for the individual's time away from work). Licensees report that, on average, the administrative effort in determining FFD suitability for access (paperwork and administration only, not including testing) requires an average of 15 minutes per applicant. It is assumed that the annual savings of eliminating the suitable inquiries as allowed by the rule revision would be \$423.90 per FFD program ([4 suitable inquiries x .25 hours x \$44.78 per hour] plus [4 pre-access tests x \$94.78 per test]). The reduced random testing would save an estimated \$2,369.50 per FFD program (50 people x 50 percent random testing rate annually x \$94.78 per test). Eliminating blind proficiency testing for approximately three percent of the total number of reduced tests (another change analyzed in the discussion of the revisions to Section 2.8 of Appendix A to Part

³¹ Average utility worker wage rate derived from information presented in NUREG/CR-4627, Abstract 6.3, Table 4.1. The average 1988 base wage rate was \$16.56. With a multiplier of 2.0 for fringe benefits, this wage rate was \$33.39 per hour. Inflating to 1995 costs and adding a utility labor inflation index of 0.8 percentage points, the estimated average 1995 utility worker wage rate is \$44.78 per hour.

26) provides additional potential cost savings. The additional cost savings from reduced blind proficiency testing would be an estimated \$56.55 ([4 pre-access tests plus 25 random tests x .03] x \$65.00 per test). The total cost savings of the rule revision would be \$2,849.95 (\$423.90 plus \$2,369.50 plus \$56.55), or approximately \$2,800. The total estimated annual industrywide savings is estimated to be \$207,200 (74 FFD programs x \$2,800 per program).

Summary of Cost Estimates for Section 26.2. The total estimated first-time cost for each licensee affected by the rule change is \$1,038.80 (\$494.04 [initial awareness training plus supervisory training] plus \$544.76 [pre-access testing]) for licensees that add four people to their program, and \$377.98 for licensees that add two people to their program (\$105.60 [initial awareness training] plus \$272.38 [pre-access testing]), or approximately \$1,100 and \$400 per program, respectively. The total industrywide initial cost is estimated to be \$16,800 (\$1,100 per program x two FFD programs plus \$400 per program x 37 FFD programs) or approximately \$17,000.

The total recurring annual costs for random testing that this rule change will create is estimated to be \$272.38 for licensees that add four people to their program, and \$136.19 for licensees that add two people to their program, or approximately \$280 and \$140 per program, respectively. The total annual recurring industrywide cost for adding fitness-for-duty personnel is estimated to be \$5,740 (\$280 per program x two FFD programs plus \$140 per program x 37 FFD programs), or approximately \$6,000. The total estimated annual industrywide savings for eliminating duplicative testing would be \$207,000.

26.3 Definitions

This section is modified to clarify definitions of some terms, to make terms and definitions more consistent with those used by other Federal agencies (including the Substance Abuse and Mental Health Services Administration and the Department of Transportation), to provide new definitions to support other sections of the rule, and to remove three terms, “random test,” “follow-up testing,” and “suitable inquiry,” because they are already clear and more fully defined in the text of the rule. In addition, several terms have been moved to this section from Section 1.2 of Appendix A because they first appear in the main body of the rule.

There are no cost impacts associated with the new definitions that are added to this section of the rule beyond those incurred in revising FFD policies and procedures, which are covered under § 26.20.

26.4 Interpretations

There are no changes to this section.

26.6 Exemptions

There are no changes to this section.

26.7 Communications

A new section, “Communications,” similar to existing sections in other 10 CFR Parts, is added to ensure that communications with the NRC are processed properly. The addition of this section has no cost implications.

26.8 Information Collection Requirements

The deletion of Section 26.8 (c) will have no cost implications.

26.10 General Performance Objectives

The current performance objective for a “drug-free workplace” has been deleted because it is ambiguous and could be read as prohibiting valid onsite use of over-the-counter drugs and prescription drugs even though they are in amounts that would not cause impairment and would not exceed any cut-off values in Part 26. This change will have no cost implications..

26.20 Written Policy and Procedures

Revisions to Section 26.20 (a) clarify the NRC's original intent that licensees provide a short, concise summary of the licensee's fitness-for-duty program which would be distributed to personnel included within the scope of the rule. It has been noted during inspections that a few licensees had incorporated their FFD policy into several procedures that were not readily available to employees. Therefore, the change is necessary to preclude any future misunderstanding. The NRC's intent remains that licensees publish a statement notifying employees of the policy as is required by the Drug-Free Workplace Act of 1988. This summary statement should make covered employees unmistakably aware of their FFD program's expectations and of the consequences that can result from not adhering to FFD policy. This section is also revised to require written policy and procedures explicitly prohibiting off-site involvement with illegal drugs or the abuse of legal drugs. There were some isolated problems in this regard that were identified during the inspection process. This change also clarifies the original intent of the rule and reflects current practice. The change is necessary to preclude any future misunderstanding. There are no cost impacts associated with these rule changes. In addition, other revisions to Section 26.20 (a) add off-site involvement with illegal drugs, subversion of the testing process, and refusal to provide a specimen for testing as fitness-for-duty concerns. The first of these additions is clarification of licensee responsibilities to consider off-site action as an indicator of illegal drug problems that should be followed up. The addition should not impact costs of the program for licensees.

Revisions to Section 26.20 (c) and (d) clarify certain wording in the sections. An addition to 26.20 (d) (3) and (4) requires immediate follow-on actions as well as procedures to be followed in the event of an employee's attempt to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), or substituting specimens, or in cases where a person being tested refuses to provide a specimen for analysis. There are no significant cost impacts that would be associated with these rule changes.

Section 26.20 (e) is revised to require persons who are called in to work on an unscheduled basis to declare whether they consider themselves to be fit to perform assigned tasks. This section currently requires called-in employees to state whether they have consumed alcohol within the licensee's pre-duty abstinence period. The revision will also assure employees an opportunity to express their own opinion as to whether they believe themselves fit to perform assigned tasks in view of fatigue, illness, use of medications, or consumption of alcohol. In some situations, this requirement could afford licensees some burden reduction and protection in that, if a called-in person is unfit and

tells the licensee of this condition when contacted, the licensee would not have to get that person home safely and call in a replacement which may delay the appropriate response to the situation that caused the call-in. In addition, this revision may reduce the chance that licensees would be subject to civil suits arising from accidents while the called-in people are in travel. This rule revision clarifies the original intent of the rule and therefore no cost impacts are estimated.

A new Section 26.20 (f) is added to the rule. It allows licensees to credit unescorted access status granted by other licensees. Such individuals must be covered by the random testing and behavioral observation programs of either the original licensee employer or that of the host licensee. As currently written, the section is unclear as to whether a licensee needs to audit another licensee's program before granting unescorted access to that licensee's employee. The addition eliminates that question as well as facilitate the interchange of employees among licensees in, for example, situations where a "peer evaluator" from one licensee works with a second licensee. Thus, the change provides the licensees with more flexibility.

The added flexibility provided by this new Section 26.20 (f) may in certain instances represent potential cost savings to licensees. Although there may be an appreciable number of visitors from other licensees, this analysis will assume that the change will affect only ten people each year on Institute of Nuclear Power Operations (INPO) inspections and related visits. This revision eliminates any question as to the need for a licensee to audit another licensee's program before granting unescorted access to that licensee's employee. It is assumed that each person would be subject to testing and behavioral observation programs of either his or her employer or that of the host licensee, and that each visit would be three weeks in duration, or 30 person weeks total. The rule change eliminates an estimated one hour in staff time and one hour processing time for each person at each reactor unit or nuclear fuel facility. The estimated cost savings would be \$78.17 (\$44.78 per average utility worker-hour plus \$33.39 per clerical employee-hour), or approximately \$100 per reactor/nuclear fuel facility. The total estimated industrywide annual savings would be \$11,200 (\$100 x 112 reactors/nuclear fuel facilities), or approximately \$11,000.

Overall Policy Revision Costs. Section 26.20 currently requires licensees to maintain written FFD policies and procedures. Among the major policy revisions in the rulemaking in addition to those in Section 26.20 is a new requirement in Section 26.24 (h) pursuant to which confirmed blood alcohol content readings of less than 0.04 percent can be declared positive alcohol test results depending on how long the tested person has

been at work. Staff expects that licensees will modify their written FFD policies with respect to this and other rule changes.

Staff assumes that review of these policy changes would entail a one-time review by the FFD program manager, the MRO, and a licensee manager, as well as some clerical time to incorporate these changes into the current FFD program policy. It is assumed that this review would entail three hours of an FFD program manager's time at \$70.71 per hour, three hours of an MRO's time at \$94.64 per hour, three hours of a licensee manager's or designate's time at \$70.71 per hour, and three hours of a clerical assistant's time at \$33.39 per hour. The total cost per FFD program would be \$808.35, or approximately \$800. The total industrywide cost of this one-time review would be \$59,200 (\$800 per program x 74 FFD programs).

Overall Procedure Revision Costs. The revisions include no new requirements for major procedure revisions. It is expected, however, that licensees would incorporate minor administrative procedure revisions into their FFD programs as appropriate, e.g., reporting requirements for test results, MRO medical review procedures, and changes to various technical guidelines contained in Appendix A of the rule. Staff estimates that the total cost for such minor procedure revisions would be \$1,189.10 per FFD program or approximately \$1,200.³² The total estimated industrywide cost for this one-time procedure revision would, therefore, be \$88,800 (\$1,200 per program x 74 FFD programs) or approximately \$89,000.

Summary of Estimated Savings and Costs for Section 26.20. The revision to Section 26.20 (f) that allows licensee to credit unescorted access status granted by other licensees would produce an estimated cost savings of approximately \$100 per reactor/nuclear fuel facility. The total estimated industrywide savings would be \$11,200 (\$100 per unit x 112 reactors/nuclear fuel facilities), or approximately, \$11,000. The total estimated policy and procedure revision cost per program would be \$2,000 (\$800 plus \$1,200). The total industrywide cost of these revisions would be \$148,000 (\$2,000 per program x 74 programs).

³²Staff considers any changes to the FFD procedures to be of an incremental nature. Therefore, these changes are considered a simple routine procedure revision. Using the best estimate provided in NUREG/CR-4627 (Revision 1), Abstract 2.2.2., "Industry Costs For Writing Or Rewriting Procedures," Table 4.1, "Generic Cost Summary Table For Writing Or Rewriting Procedures," this procedure change would cost each site an average of \$900.00 in 1988 dollars, or \$1,189.10 when inflated to 1995 dollars using the Projections of Gross National Product Price Deflator in Abstract 6.3, "Time-Related Cost Adjustments," Table 4.3.

26.21 Policy Communications and Awareness Training

Some minor wording changes are made to Section 26.21 (a) which clarify the original intent of the rule and are expected to have no cost impact on licensees.

The rulemaking revises Section 26.21 (b) to allow licensees to accept the generic portions of training of individuals who have been subject to another Part 26 program and who have had initial or refresher training by another licensee within the 24 months prior to assignment, provided that site-specific training is completed. Policy communications and awareness training covers a number of common areas that are consistent across licensee programs. As a result, it is not necessary for a worker to repeat the entire training when he or she moves to another site. Because there are some differences among licensees, new personnel should be trained in those aspects of licensee programs that are particular to the site. This change facilitates the efficient movement of personnel among licensees without jeopardizing public health and safety. Some licensees may realize some savings by foregoing certain portions of training, thereby reducing training costs and allowing the worker to report for duty sooner.

Another revision under 26.21 (b) decreases the frequency of FFD policy awareness refresher training from every 12 to every 24 months. However, the Commission would expect that FFD program changes, as mandated by final rulemaking, will be communicated to all affected workers before the changes are implemented. NRC FFD inspections have found employees to be generally aware of the policies and potential for FFD problems. In addition, the material presented in this training is relatively straightforward and is not expected to change significantly over time. Refresher training on a nominal 24-month frequency would be sufficient to keep personnel covered by the rule aware of FFD program policy and procedures.

The changes to Section 26.21 (b) represent a potential cost savings to licensees. It is assumed that refresher training is extended to once every 24 months and that, out of the total testing population, 15 percent of all licensee employees and contractors with previous training are transferring between sites due to outages, other assignments, and transfers. The average reactor/nuclear fuel facility population covered by the FFD rule is estimated to be 979 people; so an estimated 147 people per unit are assumed to be transferring annually. Furthermore, it is assumed that the frequency of transfers is as follows:

- 20 percent of the 147 people transfer 4 x annually, or 118 total transfers
- 20 percent of the 147 people transfer 3 x annually, or 89 total transfers
- 20 percent of the 147 people transfer 2 x annually, or 59 total transfers

40 percent of the 147 people transfer 1 x annually, or 59 total transfers
Total Transfers: 325

Of these 325 annual transfers per facility it is assumed that ten percent, or 33, would be transfers of supervisors. Supervisorial transfers are addressed in the discussion of revisions to Section 26.22 below. Non-supervisorial transfers would, therefore, be 292 in total. The savings in staff time due to reduced training would be \$13,075.76 (292 transfers x 1 hour training x \$44.78 per hour), or approximately \$13,100 per unit. The total estimated industrywide savings would be \$1,467,200 (\$13,100 per unit x 112 reactors/nuclear fuel facilities), or approximately \$1,467,000.

The other revision of Section 26.21 (b), which decreases the required frequency of refresher training for personnel covered by the rule from once every 12 months to once every 24 months, may represent a potential cost saving to licensees since it would effectively reduce FFD refresher training costs by fifty percent. It is estimated that this rule revision could save licensees \$61,000 annually, for a total estimated industrywide savings of \$6,832,000 (112 reactor/nuclear fuel facilities x \$61,000 per reactor/nuclear fuel facility).³³

26.22 Training of Supervisors and Escorts

Clarifications are added to this section with regard to FFD training of supervisors and escorts before assignment to supervisory duties. These clarifications are not expected to have a significant impact on the costs of FFD programs.

Revisions to Section 26.22 (c) permits licensees flexibility by extending refresher training from a 12-month frequency to a 36-month frequency, if an objective written examination is given to supervisors every 12 months in the interim period. Supervisory FFD training ensures that supervisors and escorts will be able to successfully fulfill their key role in implementing FFD programs. Supervisors and escorts must, for example, be continuously able to recognize drug use or degradation of performance of the people working around them. To remain effective they must be made aware of the most current techniques for effectively performing these functions. A written exam that demonstrates an adequate knowledge of pertinent FFD issues and material to be used in lieu of refresher training for supervisors and escorts in two out of every three years should decrease licensee administrative expenses without compromising the effectiveness of

³³In a letter to Brian K. Grimes, NRC, from Thomas E. Tipton, NUMARC, September 20, 1991, annual FFD refresher training costs were estimated to be \$100,000 per reactor unit in 1990, or \$122,900 inflated to 1995 dollars.

FFD programs. Refresher training would be mandatory at least once every 36 months. Although there may be potential cost savings in extending supervisory training from once every 12 months to once every 36 months, there may also be additional costs associated with the development of an objective examination applied annually in the interim period. Many licensees already administer examinations to demonstrate knowledge. In cases where licensees have not administered objective examinations, the saving from reduced refresher training may be offset by costs incurred in developing and administering the examinations. Overall, there are likely to be some indeterminate savings afforded by this rulemaking action.

Another addition to Section 26.22 (c) allows licensees to accept training of supervisors and escorts who have been subject to Part 26 requirements and who have had initial or refresher training within 12 months prior to assignment as long as the site-specific training requirements are completed prior to granting of access. This revision facilitates the movement of supervisory personnel among licensees and decrease licensee costs for training people in a number of common areas that are consistent across licensee programs. As noted previously, because there are some differences among licensees, personnel newly joining a particular licensee should be trained in those aspects of the licensee's program that are site specific. Likewise, the Commission expects that changes in the FFD program that affect a supervisor's responsibilities, such as procedures for initiating corrective action, will be promptly communicated to the supervisors.

As discussed in Section 26.21 (b), it is estimated that a total of 33 supervisory transfers would be made per reactor/nuclear fuel facility. The estimated cost savings would be \$2,333.43 (33 transfers x 1 hour training x \$70.71 per hour), or approximately \$2,300. The total estimated industry wide savings would be \$257,600 (112 units x \$2,300 per reactor/nuclear fuel facility), or approximately \$258,000.

26.23 Contractors and Vendors

This section currently requires that personnel who have been denied access or removed from activities within the scope of Part 26 for violations of an FFD policy will not be assigned to activities within the scope of Part 26 without the knowledge and consent of the licensee. The experience of the first eight years of FFD program operations has indicated instances where contractors sent personnel with a known history of substance abuse onsite without informing the licensee. In one instance, the contractor was aware of the requirement but sent the worker to the site anyway. In another instance, the contractor was not aware of the worker's history due to the information protection requirements in Section 26.29. This section should be clarified to ensure that people having a history of substance abuse do not receive these assignments without the

licensee's knowledge and consent. This revision expands contractors' and vendors' responsibility to report known information to licensees pertaining to their employees' backgrounds thereby further ensuring the integrity of power plant operations. A companion change to Section 26.29 permits disclosure of test results to the contractor employers. These changes would minimize the need for licensees to replace contractor personnel who have a substance abuse history unknown to the contractor being sent to a site, thereby causing some minor indeterminate savings.

26.24 Chemical Testing

There are several revisions to Section 26.24, including four revisions to Section 26.24 (a) (1). These revisions are intended to rectify inconsistent interpretations of testing requirements that have appeared across the industry during the eight years of FFD program operations. The first revision to Section 26.24 (a) (1) clarifies the Commission's original intent to explicitly prohibit granting unescorted access to an individual until a negative pre-access test result has been obtained. This clarification should not have a cost impact on licensees.

A second revision to Section 26.24 (a) (1) allows licensees to consider any drug and alcohol test meeting Part 26 standards and performed within the 60 days prior to granting of unescorted access to serve as a pre-access test. This revision is intended to reduce unnecessarily redundant testing. For instance, tests performed by another licensee or under a testing program required by the U.S. Department of Transportation would qualify as a pre-access test under this revision. In such circumstances, the NRC would expect that licensees would use a dependable means of confirming that the person seeking access had actually been tested. This could be accomplished by the electronic exchange of pertinent information among licensees using a computerized data base that the industry is currently considering for implementation. Many licensees use contractors or licensee employees who work at different nuclear power plants, especially during outages.

It is expected that waiving test requirements for those people who have received a drug and alcohol test meeting Part 26 standards would provide some savings to licensees in reduced testing and staff time costs. In 1995, 79,305 pre-access tests were conducted at licensee power plants (NUREG/CR-5758, Vol 6). It is assumed that 10 percent of applicants per reactor have been tested in the previous 60 days, or approximately 72 applicants per reactor/nuclear fuel facility $[(79,305 \text{ pre-access tests divided by } 110 \text{ reactors}) \times 10 \text{ percent}]$. Assuming an average cost of \$50 per test and assuming that each test takes one hour at an average licensee personnel wage rate of \$44.78 per hour, the estimated potential cost savings per test would be \$94.78, plus cost savings from reduced blind proficiency testing. The estimated annual cost

savings for pre-access testing per reactor would be \$6,828.16 (72 tests x \$94.78). Eliminating blind proficiency testing for approximately three percent of the total number of reduced tests would provide additional potential cost savings.³⁴ The additional cost savings from reduced blind proficiency testing would be an estimated \$140.40 ([72 tests x .03] x \$65.00 per test). The total annual cost savings per reactor/nuclear fuel facility would be \$6,964.56 (\$6,824.16 plus \$140.40), or approximately \$7,000 per reactor/nuclear fuel facility annually. The total estimated annual industrywide savings would be \$784,000 (\$7,000 per reactor/nuclear fuel facility x 112 reactors/nuclear fuel facilities).

In addition, this rule change enables some licensees to reduce their overall outage periods due to the earlier availability of some workers, thereby reducing their direct non-labor outage costs. Significant cost savings could also result from reductions in replacement purchase power costs saved by reducing outage periods by allowing pre-access applicants to begin work sooner. These potential cost savings are not readily quantifiable.

A third revision to Section 26.24 (a) (1) allows licensees to waive the pre-access test requirement if the applicant has been covered by a program meeting the requirements of Part 26 for at least thirty days during the 60 days immediately previous to the granting of unescorted access, as long as the applicant has no history of substance abuse. Assuming conservatively that, in addition to the 10 percent tested during the previous 60 days (see above), 10 percent of pre-access applicants per reactor were covered by the Part 26 requirements under another licensee's program for at least thirty days during the previous sixty days and have no history of drug abuse, approximately 72 applicants for access per reactor/nuclear fuel facility would not have to submit to a pre-access test [(79,305 pre-access tests divided by 110 reactors) x 10 percent]. Assuming an average cost of \$50 per test and assuming that each test takes one hour at an average licensee personnel wage rate of \$44.78 per hour, the estimated potential cost savings per test would be \$94.78, plus cost savings from reduced blind proficiency testing. The estimated annual cost savings for pre-access testing per reactor would be \$6,824.16 (72 tests x \$94.78). Eliminating blind proficiency testing for approximately three percent of the total number of reduced tests would provide additional potential cost savings. The additional cost savings from reduced blind proficiency testing would be an estimated \$140.40 ([72 tests x .03] x \$65.00 per test). The total annual cost savings per reactor/nuclear fuel facility would be \$6,964.56 (\$6,824.16 plus \$140.40), or approximately \$7,000 per reactor annually. The total estimated

³⁴Revisions to Section 2.8 (e) (2) will reduce the number of blind performance test specimens that licensees are required to submit for analysis as part of their FFD quality assurance and quality control program. After the initial 90-day period, the minimum number of blind performance test specimens would be lowered from 10 percent of all samples submitted to 3 percent, or 10 blind performance specimens, whichever is greater. In estimating cost savings that involve a reduced number of blind performance specimens, this lower proposed 3 percent rate is used as a conservative savings estimate.

annual industrywide savings would be \$784,000 (\$7,000 per reactor/nuclear fuel facility x 112 reactors/nuclear fuel facilities).

The fourth revision to Section 26.24 (a) (1) allows licensees to grant unescorted access to applicants prior to receiving a negative test result in cases where a pre-access applicant has had a negative test result on a test meeting the standards of Part 26 performed within 6 months prior to the granting of unescorted access, or has been covered by a program meeting Part 26 standards for two consecutive weeks during that 6-month period, and has no history indicating illegal drug use or the abuse of legal drugs including alcohol. This relief from the requirement for a negative test result before the granting of access is based upon industry experience of the demonstrated reliability of workers who have been covered by a rigorous program in the past. In these circumstances, the NRC would also expect that licensees would confirm the occurrence of such tests or such coverage. These revisions reiterate the importance attached to establishing individuals' fitness status before they are granted access. At the same time, these revisions allow some efficiencies borne out by industry experience in the granting of access without compromising public health and safety.

This rule change may represent substantial potential cost savings to licensees. According to some public commenters, however, most licensees will not immediately be able to take advantage of this rule change because the industry's computerized database does not now contain the specific information about employees' recent employment records that licensees will need to implement it. Nonetheless, the staff believes that the substantial savings that can be obtained by being able to grant access prior to receiving a negative test result will motivate licensees to begin gathering and disseminating the employment information they need to implement this rule change within a reasonable time. Therefore, the estimated cost savings will be included in this analysis.

For FFD programs that send specimens off-site for testing, substantial cost savings could result from eliminating the waiting period from the time a specimen is submitted until the time the negative results are provided to the licensee. The NRC staff understands that licensees currently compensate many applicants in full or in part while they await their test results. Sites conducting on-site testing would derive fewer cost savings from this rule change since they can obtain a negative test result within a relatively short period of time. It is estimated that 33 percent of the pre-access applicants were covered by the Part 26 requirements under another licensee's program for 10 days within the previous 3 months (e.g., contractors or applicants who have recently worked in the nuclear power industry). This would eliminate the waiting period for 26,170 pre-access applicants industrywide (NUREG/CR-5758, vol. 6 reported that 79,305 pre-access tests were conducted in 1995). Experience has shown that the majority of laboratories require one to three days to analyze and report test results. Using a conservative estimate, the

waiting time for access for these applicants would be reduced by one day (the time for the off-site laboratory to analyze and report back the results to the licensee). It is assumed that licensees attempt to make productive use of pre-access applicants awaiting test results whenever possible. Therefore, a conservative estimated savings of four hours per applicant is assumed. The savings would thus be an estimated four hours of labor cost for each of the 26,170 pre-access applicants industrywide, or 238 pre-access applicants per licensee (26,170 divided by 110 reactors).³⁵ Assuming a standard utility labor rate of \$44.78 per hour, the total savings per licensee would be \$42,630.56 (238 pre-access applicants x \$44.78 per hour x 4 hours), or approximately \$43,000. The total estimated industrywide savings would be \$4,816,000 (\$43,000 per program x 112 reactors/nuclear fuel facilities).

The clarification of random testing requirements in Section 26.24 (a) (2) assures that random testing is being appropriately administered during weekends, backshifts, and holidays and that it is unpredictable and conducted at various times during the day. A few licensees that randomly tested only during weekday day shifts provided predictable gaps in testing; employees working during evenings and on weekends knew they would not be tested. The revision clarifies that persons off site when selected for testing must be tested at the earliest practical and reasonable opportunity and without prior notification. All FFD program personnel and employees being tested need to be aware that tests are truly random and unpredictable and that tests may occur during any day or night duty hours. Also, any predictable patterns of random testing must be eliminated, such as the pattern established when testing is conducted only once a week and usually on the same day each week. Courts have ruled that, unless random tests are sufficiently frequent and unpredictable, they do not provide the deterrent effect necessary to justify overcoming personal privacy considerations. These clarifications create no new random testing requirements, but instead clarify currently existing requirements. According to inspection data, licensees are currently testing on backshifts and holidays in compliance with this requirement; where they haven't, enforcement action has been taken. Therefore, this rule clarification will ensure compliance with this important legal aspect of random testing and is expected to have no significant cost impact on licensees.

Section 26.24 (a) (3) continues to require for-cause testing to be conducted as soon as possible after any observed behavior that indicates possible substance abuse. This requirement is clarified to indicate that tests in response to an observed physical condition that creates a reasonable suspicion of possible substance abuse should be considered for-cause tests. This

³⁵Licensees with on-site testing programs have reported significant cost savings in eliminating the waiting time needed to receive a test result report from an off-site laboratory, as well as reductions in specimen transportation costs. Even on-site testing facilities may need several hours before reporting test results to the licensee. The estimate of one day needed to send a specimen off-site for analysis and to receive a report from the laboratory is considered a conservative estimate for purposes of estimating cost savings resulting from the rule change.

clarification is in response to frequent questions from licensee staff regarding the appropriate categorization of these tests. A revision to this section provides some flexibility and make explicit that the licensee has two hours, except under documented unusual circumstances, to perform the alcohol test after such event and eight hours to perform the drug test after such event. This change is intended to accommodate situations where no collection personnel are on site and need to be called in or the individual transported to another location for testing. It is in the best interests of both the licensee and the worker in this situation to collect the specimens as soon as possible so that the process of evaluating the perceived impairment may proceed rapidly. A shorter time is specified for alcohol because of the more rapid metabolism of this substance. The revision also requires that the worker's unescorted access status be suspended until he or she is pronounced fit for duty based on a management and a medical determination of fitness. This change assures that individuals who are impaired for any reason are not unescorted in the protected area of a nuclear power plant. Further, removal due to impairments that are not the result of a violation of the licensee's FFD policy are not to result in punitive action. All three of these revisions clarify the rule's original intent and are expected to have no cost impact of any significance on licensees.

Section 26.24 (a) (3) also is revised to allow people who are tested for-cause for alcohol to return to duty while awaiting negative urinalysis results if the results of the alcohol test are negative and they are determined to be fit for duty. Although data concerning the number of for-cause tests conducted because of suspected alcohol use and the number of positive test results are not available, these numbers may be estimated. In 1995 there were 763 for-cause tests, or approximately 11 for-cause tests per power reactor FFD program (763 tests divided by 72 power reactor FFD programs). Licensees report that the majority of the for-cause tests are based on indications of alcohol use. Therefore, it is assumed that 80 percent of for-cause tests (9 tests) are for suspected use of alcohol. Licensees also report that, since many of the for-cause tests for alcohol are based on indications such as the odor of alcoholic beverages and are not necessarily due to gross aberrations in behavior, many of the tests are declared negative. The for-cause confirmed positive test rate in 1995 for all substances was 18.22 percent. In 1995, 17.17 percent of the confirmed positive results for all tests (random, pre-access, for-cause, and periodic tests) were caused by alcohol. Therefore, for purposes of this analysis, it is conservatively assumed that 20 percent of the 9 for-cause tests based on indications of alcohol use would produce a positive result (2 per program) . It is also assumed that in 50 percent of the remaining for-cause tests for suspected alcohol use unescorted access would be suspended due to a management or medical determination of fitness. This would result in three of the total 9 for-cause tests for suspected use of alcohol per FFD program being declared negative ($7 - (.50 \times 7)$). Licensees report that the time awaiting a negative urinalysis test result may take up to four days, during which time the person who was tested for-cause for alcohol is removed from normal duties but compensated none the less. It is assumed, on average, that for each of these three

people, two nonproductive but compensated days are spent awaiting a negative test result. The labor savings from eliminating the time pending urinalysis test results for those people who test negative for suspected alcohol use would be \$2,149.44 per FFD program (3 people x 16 hours x \$44.78 per hour), or approximately \$2,000. The estimated annual industrywide savings would be \$148,000 (74 FFD programs x \$2,000 per program).

The revisions to Section 26.24 (a) (4) specify follow-up testing requirements for persons whose unescorted access is reinstated in compliance with Section 26.27. They would move a related requirement pertaining to the frequency and duration of follow-up testing from Section 26.27(b)(4) to the more appropriate location of Section 26.24(a)(4) to clarify the original intent of the rule. It is the NRC's policy that until a person can show that he or she has abstained from substance abuse for at least three years, there is a continuing probability of resumption of substance abuse that is too high given the exceptional safety concerns of the nuclear power industry. This high probability is the basis of this rule's requirement for follow-up testing. In addition, the revision to Section 26.24 (a)(4) provides an administrative clarification consistent with revisions to Section 26.27 (c), which includes acts or attempted acts of subversion as FFD policy violations. The revision to Section 26.24 (a)(4)(ii) includes people who are granted unescorted access after previously having had their access revoked.

This requirement results in a minimum of seven tests per licensee employee enrolled in a follow-up testing program in the first calendar year of a follow-up testing program and four tests per year thereafter for the remaining period. Staff's review of program performance data suggests that licensees already meet or exceed the requirements of the rule change. In NUREG/CR-5758, vol. 6, licensees reported a total of 354 FFD violations by licensee employees and contractors in 1995, excluding pre-access violations and periodic testing violations. It is known that a few licensees terminate employees based on a first positive test and that most licensees do not provide rehabilitation services to contractor employees. It is assumed that only 20 of the 257 contractor positives would receive follow-up testing, i.e., 137 licensee employees and 20 contractors, or 157 workers would receive follow-up testing. During the same time period, licensees reported that a total of 3,262 follow-up tests were conducted. These program performance data suggest that the follow-up testing by most licensees is at least as stringent as the rule currently requires. Also, the regional inspectors have confirmed that they do not know of any licensee not already conducting follow-up testing which does not meet or exceed the requirement of the current rule. The current level of follow-up testing is also likely to cover whatever follow-up testing that may be required of the very few employees who have attempted to subvert the testing process, had their access revoked for three years under Section 26.27 (c), and been granted access after the three-year period. These clarifications of the original intent of the rule are expected to have no cost impact of any significance on licensees.

A new Section 26.24 (a) (5) adds a fifth type of required chemical testing referred to as “return-to-duty” testing. In its current form, the rule does not clearly state the Commission's intent that licensees should test personnel having unescorted access when they return to work after extended absences or after being removed for cause. The NRC staff is aware that most, but not all, licensees are already testing people when they return to their sites in these circumstances. This is consistent with the original intent of the Section 26.27(b)(2) and (b)(4) requirement for a medical assurance of fitness in that a return-to-duty test should be an essential part of such assurance. The change clarifies the NRC's original intent. Return-to-duty testing requires licensees to test personnel who seek to regain access to the protected area after an absence from the possibility of being tested under the particular licensee's FFD program for more than 60 days, or after being removed for cause. The 60-day period was chosen in order to be consistent with the current pre-access limitations in NUMARC 91-03, “Nuclear Power Plant Personnel Access Authorization Data Exchange Guidelines,” dated October 1992, one of several documents that describe how the NRC’s Access Authorization Program is to be implemented. The industry guidelines provide that to be issued a badge in a situation where an individual has an existing access authorization, the individual must either be currently covered by an FFD program including random testing, or have satisfactorily completed pre-access drug and alcohol testing within 60 days prior to badging, and be subject to a behavioral observation program and FFD program.

This new section furthermore requires that a negative test result must be obtained before the person is granted access unless the person either has had a negative test result on a test that meets Part 26 standards during the past 6 months or had been covered by a program meeting Part 26 standards for two consecutive weeks within the previous six months. As for pre-access testing, tests performed by another licensee or under a testing program required by the U.S. Department of Transportation are examples of tests that would qualify as return-to-duty tests under this revision. In such circumstances, the NRC would expect that licensees would use a dependable means of confirming that the person seeking access had actually been tested or been covered by another program. This could be accomplished, for example, by the electronic exchange of pertinent information among licensees using a computerized data base that the industry is currently considering.

Based on limited information, the NRC staff understands that approximately forty percent of licensee programs are currently calling people in for random tests from long distances, to ensure that they comply with the requirement that all people in the random testing pool have an equal probability of being selected and tested as required by the current rule, rather than waiting to test when the people are next on site. The revisions to Sections 26.24 (a) (1) and (2), combined with the new return-to-duty testing, are intended to eliminate this current unnecessary and costly practice of licensees requiring immediate testing in these circumstances. These

revisions are intended to clearly indicate that licensee programs should take measures such as flagging off-site workers' badges for testing when they next come on site rather than requiring them to immediately come to the site for testing. Information obtained from the industry indicated industrywide average of approximately 500 licensee and contractor employees per reactor/nuclear fuel facility who work off site and have infrequent access. Of this number, it is estimated that 380 people work at a reasonable proximity to the plant such that they would be reasonably available for testing if they are chosen for random testing. The remaining 120 people work sufficiently far from the plant that they cannot reasonably be brought to the plant upon being chosen for random testing. Applying the 50 percent random testing rate, these 120 people would be subject to approximately 60 random tests per year. The revisions to the Section 26.24 testing requirements would be expected to produce savings at 45 reactors/nuclear fuel facilities (112 reactors/nuclear fuel facilities x 40 percent) because 60 employees per year at each of these sites will no longer be required to make a special trip to the site for random testing. These savings would accrue due to a reduction in costs of an estimated four hours of travel time to and from the site, one hour for testing and associated travel expenses. The estimated savings would be \$14,634 [60 people x five hours x \$44.78 per hour] plus [60 people x \$20 travel cost per person for the round trip], or approximately \$14,600 per reactor/nuclear fuel facility. The annual industrywide cost savings would be \$657,400 (45 reactors/nuclear fuel facilities x \$14,600 per FFD program).

As noted above, the staff is also aware that many licensees are currently routinely testing personnel having unescorted access when they return to the site after extended absences. Such people can include utility headquarters staff, contractors, and consultants who have unescorted access but come to the site only infrequently and, therefore, may not have been subject to testing under that particular site's program for extended periods. While much of this testing is quite appropriate, the new return-to-duty testing requirements are designed to eliminate some current testing that is not necessary to achieve the rule's safety objectives. (Staff is aware that some licensees test people returning after absences of more than two weeks or longer, but practices such as these which exceed the rule requirements are not considered in this analysis). This revision, for example, relieves the testing requirements for a person seeking to regain access who has obtained a negative drug and alcohol test at another licensee during the past two months. It is assumed that 175 people per reactor/nuclear fuel facility are currently being tested when returning from extended absences each year. Of these 175 people, it is estimated that 25 percent have had a negative test result during the past 60 days. The estimated annual cost savings for reduced testing per reactor/nuclear fuel facility would be \$4,265.10 (45 tests x \$94.78 per test). Eliminating blind proficiency testing for approximately three percent of the total number of reduced tests (as discussed previously under revisions to Section 26.2) would provide additional potential cost savings. The additional cost savings from reduced blind proficiency testing would be an estimated \$87.75 ([45 tests x .03] x \$65.00 per test). The total annual cost

savings per reactor/nuclear fuel facility would be \$4,352.85 (\$4,265.10 plus \$87.75), or approximately \$4,400. The annual industrywide cost savings would be \$492,800 (112 reactors/nuclear fuel facilities x \$4,400 per reactor/nuclear fuel facility).

In addition, some of the remaining 131 people (75 percent of the 175 people) who would still need to take a return-to-duty test would benefit by not having to wait from the time a specimen is submitted until the time the negative test results are provided to the licensee. Section 26.24 (a) (5) allows immediate access in cases in which the person has either had a negative test result within six months prior to the reinstatement of unescorted access or has been covered by a program meeting Part 26 standards for two consecutive weeks during that period. This relaxation of requirements is similar to the change to Section 26.24 (a) (1) discussed above. Like that revision, licensees may not be immediately able to implement this rule change due to lack of appropriate employment information. The staff has included estimated cost savings for this revision, however, because it expects the industry will begin acquiring the information needed to implement the rule change in order to take advantage of the potential savings.

It is assumed that 66 people, or one-half of the remaining 131 people, will have this status. As discussed previously in Section 26.24 (a) (1), a waiting time of four hours is a conservative estimated savings in this situation. This four-hour assumption encompasses conditions at all licensee programs, including those that receive test results back very quickly from their own on-site testing facilities and those that may have to wait considerably longer periods for results to be returned from HHS-certified laboratories. The savings would thus be an estimated four hours of labor cost for each of the 66 people seeking to regain access. Assuming a standard utility worker hourly rate of \$44.78 per hour, the total savings per reactor/nuclear fuel facility would be \$11,821.92 (66 people x 4 hours/person x \$44.78 per hour) or approximately \$11,800. The total estimated annual industrywide savings would be \$1,321,600 (112 reactors/nuclear fuel facilities x \$11,800 per reactor/nuclear fuel facility).

The total estimated annual industrywide savings of the rule revision would be \$2,471,400 (\$657,000 plus \$492,800 plus \$1,321,600).

Section 26.24 (a) (5) also requires that workers seeking to regain access after having been denied access under Section 26.27 (b) be required to take a return-to-duty test and obtain a negative result before being granted access. The requirement for return-to-duty testing in such cases is a clarification of the NRC's original intent and is consistent with DOT return-to-service testing (where the positive rate for this type of testing in 1994 was 2.8 percent). These are people who knew they would be tested and that, if the results were positive, they would not get their jobs back. It creates industry consistency for a practice that most licensees have already instituted and provides additional assurance of workforce fitness. The NRC staff understands that virtually

all licensees are already testing people seeking to regain access after a FFD policy violation as the Commission originally intended. Therefore, this requirement would create no new costs.

In the case of extended absence, it is assumed that a maximum of 5 people per reactor/nuclear fuel facility (which includes contractors and vendors) may be on extended absence for periods of 60 days or more each year and are not covered by any program meeting the requirements of Part 26 (e.g., extended vacation, maternity leave, or other leave-of-absence). Assuming an average test cost of \$94.78 (1 hour of labor x \$44.78 per hour plus \$50.00 per test), the total estimated annual cost per reactor would be \$473.90 (5 tests x \$94.78 per test), or approximately \$500. Although it is known that many licensees are already conducting such tests, the total estimated annual industrywide cost is estimated to be \$56,000 (112 reactors/nuclear fuel facilities x \$500 per reactor/nuclear fuel facility).

Revisions to Section 26.24 (d) clarifies staff qualification and quality control requirements for on-site testing facilities. These changes leave the section's requirements essentially unchanged from the amendment to the paragraph published by the NRC on August 26, 1991 (56 FR 41922). The rule revisions are expected to have no cost impact on licensees. An additional change to this section establishes a new requirement for specimen quality that is addressed in Section 2.7 (e) of Appendix A to Part 26. The costs associated with this new requirement are covered under that section of the Appendix.

A new Section 26.24 (e) requires licensees to minimize the time between testing notification and the actual specimen collection to minimize the opportunities to subvert the test. Staff understands that operational necessity may sometimes prevent the person to be tested from immediately reporting for testing and that being escorted between notification and test may be an unreasonable burden in most situations. Several licensees have reduced the notification time, primarily using the supervisor to notify the individual when he or she can be spared. The staff is aware, however, that some licensees release workers for tests in a manner that allows them ample opportunity to obtain materials that might subvert the testing process by, for example, acquiring adulterants or surrogate samples kept in a locker or vehicle. This revision is a very important measure that could substantially reduce the potential for subversion of the testing process throughout the industry. As such, this proposal forms a cornerstone of the group of rule revisions that are intended to minimize ongoing testing subversion.

Based on reported licensee experience, staff are aware that licensees that are not stringent in minimizing the time between notification and testing have higher rates of dilute specimens than those licensees that minimize this period. One expected direct effect of this revision, therefore, is a reduction in the total number of specimens that would be dilute or otherwise suspected of subversion. Data collected by the National Laboratory Certification

Program (NLCP) can be used to estimate this effect. These data indicate that 7.6 percent of specimens in a DOT survey were dilute.³⁶ This study also determined that approximately 10 percent of these dilute specimens actually contained trace amounts of drugs. Based on these data, it is assumed that approximately one percent of samples in a testing population could be dilute and be found positive for drugs. In 1995 FFD programs conducted an average of 2,085 tests. Therefore, it is assumed that 21 specimens per site may currently be dilute for purposes of subversion each year. (This revision would not reduce the number of specimens that are normally dilute due to large consumption of liquids for dietary or health reasons.)

The rule change provides some savings in fewer repeated specimen collections, fewer tests of dilute specimens, and fewer FFD program reviews of dilute specimens or specimens otherwise suspected of subversion. Currently licensees may test for specific gravity and other indications of dilution or subversion on-site, send the dilute specimens off-site for further analysis, or send all specimens off-site for analysis (at which point the HHS laboratory would determine if the specimen is dilute or otherwise appears suspicious). Some licensees may choose to have dilute specimens further analyzed through chemical testing. In all cases of dilute first specimens, however, a second specimen is collected under observed testing conditions. Due to this variation in licensee practice, it is assumed that 1) one half of the specimens per FFD program that are determined to be dilute are subjected to chemical analysis, 2) a second specimen is collected and subjected to chemical analysis in all instances where the initial specimen is dilute, and 3) each instance of a dilute specimen is investigated and analyzed by FFD program personnel. It is assumed that the cost of specimen collection is \$44.78 per specimen and the cost of testing is \$50 per specimen. It is further assumed that a review and deliberations prompted by questionable or positive specimens requires one hour of an MRO's time at \$94.64 per hour, one hour of an FFD program manager's time at \$70.71 per hour, and one half hour of a clerical staff person's time at \$33.39 per hour, or a staff time total cost of \$184.64 per hour of staff time review (1 hour x [\$94.64 + \$70.71 + (.5 x \$33.39)]).

It is assumed that the minimized period between notification and specimen collection would prevent approximately one half of the estimated 21 people who are currently diluting their specimens, or 10 people, from successfully doing so. That is, 10 people who would want to conceal their drug use would no longer be able to do so through dilution of their specimens. This, in effect, would mean that the number of dilute specimens would be reduced by 10 specimens per licensee per year. Savings would be derived from a reduction of 10 fewer second, observed specimen collections and 5 fewer chemical tests of dilute specimens (10 tests x .5). These two sources are estimated to be produce savings of \$447.80 ([10 specimen collections x \$44.78] and \$250.00 [5 tests x \$50 per test]) for each licensee each year.

³⁶Newsletter, "NLCP Dictates Perception of Adulteration Testing," 2 (5), 7-8, May, 1993.

This revision would also produce savings due to having a reduced need for FFD program staff review of questionable or positive specimens. For reasons of conservative estimation of savings, it is assumed that, under the revision, all 10 people who would have submitted intentionally diluted specimens will instead submit normal specimens that will be tested as positive for drugs. Therefore, under the revision, it is assumed that there would have to be FFD program staff review of the additional positive test results to determine whether an FFD policy violation had occurred. There would, however, also have to be some type of FFD program staff review time associated with each of these 10 people under the current wording of this section. Such review would be required for arranging for the taking of second specimens under observation, for reviewing the results of the tests of the 5 original dilute specimens that had been submitted for chemical testing, and for reviewing the test results of the second specimens (some of which may be positive results). It is assumed that the revision would result in approximately one-half hour less review time for each of the three FFD program staff members needed in each of these 10 instances. The estimated savings for this reduction in staff time would be \$923.20 per licensee (10 reviews x .5 hours x \$184.64 per hour of staff time review).

The total estimated savings per FFD program would, therefore, be \$1,621 (\$447.80 plus \$250.00 plus \$923.20), or approximately \$1,600. The total estimated annual industrywide savings would be \$118,400 (74 FFD programs x \$1,600 per program).

The revision to Section 26.24 (f) (formerly Section 26.24 [e]) requires MROs to complete their review of test results “as soon as practicable” rather than “within 10 days after the initial presumptive positive screening test,” as currently required. The intent of the current requirement is to ensure that results are obtained within a reasonable time after specimen collection. However, industry experience has indicated in some cases that the current requirement is impractical. In order to make this requirement more effective across the industry, the NRC is proposing to require that MROs' review of laboratory test results be completed and licensee management notified “as soon as practicable” after specimen collection. This rule revision is expected to provide indeterminate savings for licensees.

The revised section also requires MROs to advise licensee management of the status of an individual's testing process if the MRO's review is not completed within 14 days after the specimen is collected. Currently, the “clock” is started when there is an initial presumptive positive screening test, thereby providing licensees that conduct on-site testing about two days less time for MRO review. This revision is intended to provide MROs with additional time to review test results consistent with a “worst case” situation. The “collection of a specimen” standard establishes a more consistent and controllable time line than “initial screening test” and the licensees conducting initial screening tests on site would then have the same amount of time to review the HHS-certified laboratories' reports as do those licensees not conducting on-site

testing. Experience has shown that the majority of certified laboratories take only 1 to 3 days from receipt of a specimen to screen and confirm tests; isolated exceptions are usually caused by 6 acetylmorphine (6-AM) testing and occasionally by unusual technical problems. The staff believes that most test results should be known to an MRO within 5 to 7 days from specimen shipment to the laboratory. The staff has no great concern where there is a legitimate technical basis for a short, reasonable delay by the laboratory, for example, where a specialized low-volume test, such as 6-AM, is done twice a week rather than every day. This revision requires, therefore, that MROs must advise licensee management of available test results and of the progress of the review if the review has not been completed within 14 days of the specimen collection.

This change should relieve pressures on MROs that have occasionally caused them to take extraordinary measures to contact tested individuals. While slightly relaxing the test result reporting requirements, the NRC would still expect MRO reviews to be completed as soon as possible, and, in accordance with a clarification of Section 2.9 (c) of Appendix A, that the MRO notify management immediately after the determination of a positive test result or other violation of FFD policy. These revisions eliminate the extra burden for licensees that conduct on-site testing and would result in indeterminate savings to all licensees. The cost savings that this revision would produce is not readily quantifiable at this time.

Section 26.24 (g) (formerly Section 26.24 [f]) is modified with several editorial changes to clarify requirements for performing screening, confirmatory, and blind performance tests at HHS-certified laboratories. These changes serve to clarify and explicitly state what is currently existing practice by licensees. In addition, this section is revised to require licensees to ensure that all collected specimens are tested and that laboratories report results for all specimen tests performed. This provision adopts, in part, the intent of a June 1994 change to the HHS Mandatory Guidelines that requires MROs to report all test results in writing so that management can assure that all collected specimens have been tested. This provision serves to clarify existing requirements to licensees to help ensure that specimens do not “slip through the cracks.” These wording changes clarify the intent of the rule and are expected to have no cost impact on licensees.

In cases where confirmatory breath tests produce a blood alcohol concentration (BAC) of 0.04 or greater, Section 26.24 (h) (formerly Section 26.24 [g]) requires the result to be declared a positive test. A revision to this section also requires a finding of positive test results if confirmatory breath tests show a BAC of 0.02 percent or greater after the employee has been on duty for two or more hours or show a BAC of 0.03 percent or greater after having been on duty for more than one hour. The addition of this procedure responds to the Commission’s concern that under the current rule it is possible for employees to begin a work shift with a BAC of 0.04

percent or greater and not receive appropriate sanctions for violation of the FFD rule from the licensee because, at the time of testing, the alcohol had metabolized below 0.04 percent BAC. The standard would minimize any potential that a person would have a positive test result without having either had a BAC of higher than 0.04 percent alcohol when on work status or consuming alcohol at any time during the work shift. The staff time needed to determine the employee's length of time on duty is expected to be minimal, and thus no additional costs are assumed for conducting the procedure. This section currently provides for a blood test to be administered if the tested person demands "further confirmation" of a positive confirmatory test for alcohol. A blood test in these circumstances has proven to be unnecessarily redundant to the second confirmatory breath test for alcohol. The NRC is, therefore, revising the purpose of blood tests so that they would be used only for providing additional information that could be considered during an appeal pursuant to Section 26.28. This rule change is expected to have no significant cost impacts.

A new Section 26.24 (i) provides licensees flexibility in cases where a medical condition renders collection of a specimen difficult or hazardous, provided that alternative methods can achieve comparable results. Some licensees have taken extreme measures trying to comply with this Section. The Commission anticipates that these occasions, which would include, for example, post-accident testing of an injured individual, would be extremely rare. This added flexibility is expected to provide indeterminate savings for licensees.

Summary of Estimated Savings and Costs for Section 26.24. The total estimated annual industrywide cost savings for the rule changes in Section 26.24 are \$9,121,400 (\$784,000 plus \$4,816,000 plus \$784,000 plus \$148,000 plus \$2,471,000 plus \$118,400) or approximately \$9,343,000. The total estimated annual industrywide costs for the rule change are \$56,000.

26.25 Employee Assistance Programs

The modification to Section 26.25 requires licensees to ensure that Employee Assistance Programs (EAPs) are designed to achieve early intervention and provide for confidential assistance. The permissive wording of the rule is changed from, "Employee assistance programs should be designed to achieve early intervention and provide for confidential assistance" to mandatory wording, "Employee assistance programs must be designed to achieve early intervention and provide for confidential assistance." This revision makes explicit the NRC's original intent for this section. Staff review of inspection reports indicate that most licensee EAPs are meeting the original intent of the rule in this regard although there have been instances where certain features of licensee EAP programs were determined to have discouraged early intervention (e.g., self-referral was considered to be a positive test result

even though no test was conducted). While actually achieving early intervention in all situations where employees' problems could adversely affect on-the-job performance may not be possible, it is reasonable to expect that all licensees' EAPs be designed to achieve this goal and not include obvious impediments to self referral such as lack of confidentiality. This revision is expected to have no significant cost impacts.

26.27 Management Actions and Sanctions To Be Imposed

Sections 26.27 (a) (1) and 26.27 (a) (2) is revised to clarify the suitable inquiry requirements before granting unescorted access to a protected area or assignment to activities within the scope of Part 26. Specifically, Section 26.27 (a) (1) is modified to require licensees to determine whether people seeking access (1) have in the last five years used, sold, or possessed, illegal drugs, or abused legal drugs (e.g., alcohol, prescription and over-the-counter drugs), (2) have in the last five years violated a fitness-for-duty policy or been denied initial assignment to Part 26 duties, or (3) have at any time been removed from activities within the scope of Part 26 due to a FFD policy violation. This limitation of some aspects of fitness history to five years will achieve consistency with the Commission's Access Authorization Rule and provide some savings to licensees.

A new Section 26.27 (a) (1) (i) clarifies that power reactor licensees do not have to obtain statements from applicants about activities involving the possession or transport of Category I nuclear materials unless the background investigation indicates that the person has been employed by a licensee authorized to possess or transport such material. By reducing the need for applicants to answer irrelevant questions, this revision may create minor indeterminate savings.

A new Section 26.27 (a) (2) requires that the licensees obtain a detailed declaration as to the type, duration and resolution of any such matter. This and the previous two revisions are intended to require the gathering of more complete information on the backgrounds of applicants for unescorted access, particularly as to potential problems with the abuse of alcohol. It should also be noted that the revisions are intended to ensure greater consistency between the suitable inquiry requirements of both the access authorization rule and the FFD rule and that one suitable inquiry for each worker should be sufficient to fulfill the requirements common to the two rules. The cost for drafting this statement is addressed under Section 26.20 policy and procedure revisions. The additional administrative cost of this revision is considered insignificant. The limitation of fitness history to 5 years will provide some indeterminate cost savings.

Section 26.27 (a) (3) (formerly [a] [2]) is modified to ensure that licensees inquire as to whether the person in question has a history of substance abuse or violation of a fitness-for-duty policy or was determined to have a confirmed positive result or used alcohol resulting in on-duty impairment. There have been a few reports of instances where a contractor or vendor employee with concurrent unescorted access to several power reactor sites had tested positive and that information was not shared with the other licensees. Although the individual was denied access by the testing licensee, the unescorted access status was continued by the other licensees. The NRC considered requiring licensees to assure that such notifications are made or to make periodic checks with other licensees and contractor employers but believes that the licensees' procedures to implement the access authorization rule (10 CFR 73.56) should facilitate the sharing of the information. Section 26.23 (a) (2) currently requires contractors and vendors to inform the licensee to which a contractor's employee is being assigned to work of any situation in which the worker has been denied access for an FFD policy violation. These and other revisions are intended to clarify the suitable inquiry requirements and are expected to have no significant cost impact on licensees.

A new Section 26.27 (a) (6) is added that makes FFD suitable inquiry requirements more consistent with those of the access authorization rule. The section allows licensees to grant employees temporary unescorted access pending final completion of the full, five-year suitable inquiry. Specifically, Section 26.27(a)(6) stipulates that temporary unescorted access may be granted when the licensee has either complied with the requirements for the granting of full unescorted access or has received and evaluated the past year's suitable inquiry results, or documented its best efforts in that regard, and initiated the suitable inquiry for the balance of the past five years. The applicant also must have passed a chemical test conducted according to the requirements of Section 26.24(a)(1). In cases in which an employee is seeking to regain unescorted access status after removal for violating a licensee's FFD policy a suitable inquiry must be conducted to determine the substance abuse history as required by Section 26.27(a) and confirm proof of abstinence provided under Section 26.27(h)(5). For persons seeking return-to-duty reinstatement after an extended absence of 30 days or more, a suitable inquiry must be conducted in conjunction with the provisions stipulated in Section 26.24(a)(5).

This addition provides some reduction in burden to licensees due to increased flexibility and consistency with the access authorization rule. The NRC assumes that most licensees currently provide temporary unescorted access to employees pursuant to the access authorization rule. For purposes of calculating the expected savings to licensees produced by this revision, it is conservatively assumed that ten percent (7,137 applicants) or approximately 99 applicants per FFD program (.10 x [79,305-7,931]) of all pre-access applicants for whom suitable inquiries must be conducted will be granted temporary unescorted access upon evaluation of suitable inquiry results of the previous year. It is also assumed that the rule change will save one full day of staff

time (based on an 8 hour work day) per applicant granted temporary unescorted access under the provisions of this revision. The estimated staff labor savings of the rule addition per reactor/nuclear fuel facility would be \$35,465.76 ($[\$44.78 \text{ per average utility worker-hour} \times 8] \times 99$) or approximately \$36,000. The estimated annual industrywide savings for allowing these employees to assume activities, pending completion of suitable inquiry investigations would be \$2,664,000 (74 FFD programs \times \$36,000).

Section 26.27 (b) (1) is revised to clarify several points. Applicants are added to the types of people to be denied unescorted access if their fitness is questionable. Violations of FFD policy (such as refusal to test or subversion of the testing process) are added as a basis for denial. The successful resolution of the impairing or questionable condition has been added as a condition to assignment of duties. Systematic review of the fitness of all personnel being returned to duty whose fitness had been deemed questionable is required. As revised, this paragraph also requires that a person who is reinstated following a policy violation must successfully complete a return-to-duty test and, where applicable, be subject to follow-up testing. These revisions reflect the original intent of the rule, and therefore no additional cost impacts are estimated.

There are various revisions to Sections 26.27 (b) (2) and (3). The first more clearly specifies the drug and alcohol testing results that are to be considered violations of FFD policy. Sanctions for alcohol would also be made consistent with those for illegal drugs. Explicit sanctions for alcohol were not contained in the original rule because the NRC wished to study the matter further. As a result of further study, the NRC concludes that impairment caused by alcohol abuse creates a safety risk that is fundamentally similar to the risk posed by the abuse of illegal drugs. Both types of abuse involve violation of explicit licensee policies, are unacceptable in the nuclear power industry, and should strongly be discouraged. Currently, licensees vary widely in their responses to alcohol abuse, with sanctions ranging from a three-day suspension to termination. The FFD rule's lack of explicit minimum sanctions for alcohol has created problems for many licensees in negotiating and defending sanction decisions. Creating minimum sanctions for alcohol abuse that are equal to those of illegal drugs will assist licensees in dealing with these situations while sending a strong message to workers about the risks involved in abusing alcohol. The costs of this policy revision is addressed under Section 26.20. This rule clarification will have no significant cost impact on licensees.

A revision to the new Section 26.27 (b) (3) imposes mandatory sanctions for alcohol abuse as well as illegal drug use and clarifies that people whose unescorted access is suspended because of policy violations and who are subsequently removed from activities covered by Part 26, but who remain employed by the licensee, still are to be covered by the licensee's FFD program with respect to behavioral observation if in a work status, chemical testing, and sanctions for

violations. In addition, a positive test result during the assessment or treatment period will constitute a second positive test. In a related matter, the NRC expects that, in those rare cases when a person is tested a second time before the results of the first test are known to the person and both results are positive, the MRO will determine whether the second test result is likely to be the result of subsequent use and, if so, determine whether the second test represents a second violation and take appropriate action. As revised, this paragraph also requires that a person who is reinstated following a policy violation must successfully complete a return-to-duty test (a negative test result must be obtained) and be subject to subsequent follow-up testing.

The intent of the above revisions is two-fold. First, these revisions would reiterate that abuse of alcohol is to be considered a serious FFD policy violation. Second, the revisions make clear the level of vigilance expected of licensee programs as to persons who are suspended for policy violations both during their suspension periods and when they return to work. These revisions reflect the original intent of the rule, and therefore no additional cost impacts are estimated.

Section 26.27 (b) (4) (formerly [3]) and (5) (formerly [4]) is revised to fully recognize the abuse of alcohol as an FFD violation. Paragraph (b) (5) is revised to more directly express its intention that a person must be determined to be fit to safely and competently perform activities under Part 26 by an appropriate licensee manager and the MRO or other qualified physician before being returned to those activities. Like other revisions to this section, these revisions are intended to elevate the importance given to licensee decisions regarding unescorted access reinstatement following FFD policy violations. This revision reflects the original intent of the rule and is consistent with the practice by most licensees. For those few licensees that are affected by this revision, added costs should be insignificant.

Section 26.27 (c) would be revised to add subversion of the testing process (to the current examples of refusals and resignations) as a cause for denial of unescorted access and an event that must be recorded and provided in response to a suitable inquiry. Each of these three examples of employee activity would be a violation of the licensee's FFD policy. A new provision would require that any attempt to subvert the testing process must result in denial of unescorted access for a minimum of three years, consistent with the sanctions required by Section 26.27 (b) (3) for a second violation of a licensee's FFD program. These revisions reflect current industry practice, clarify the original intent of the rule, and reflect the Commission's desire that violations of a licensee's FFD policy be documented and reported to reflect what actually happened, i.e., refusal to test, dilute specimen, etc., and not reported as a positive test when no test was administered. This clarification should minimize lawsuits that could result from improper reporting, and no additional cost impacts are expected. This section would also be revised to clarify that licensees are to retain records of FFD policy violations of employees that result in the

revocation of authorization to perform activities, in accordance with Section 26.71. These revisions would require consistent treatment across all licensee programs for employee activities that have resulted in varying licensee response during the first five years of FFD program operation and would reduce the burdens associated with storing records by providing a time limit on maintenance of such records. These changes are expected to result in some indeterminate cost savings to all licensees.

A revision to Section 26.27 (d) directs licensees to treat NRC contractors similarly to NRC employees if a licensee believes an NRC contractor to be under the influence of any substance or otherwise unfit for duty. This revision reflects the original intent of the rule, and therefore no additional cost impacts are estimated.

26.28 Appeals

Revisions to Section 26.28 clarify existing requirements concerning the impartiality and objectives of the review process, expand the right to appeal an FFD policy violation determination to include applicants for unescorted access, and include determination of attempts to avoid detection through subversion of the testing process. These changes should reduce legal challenges to final FFD policy violation determinations. The current rule does not provide for an appeals process for persons who test positive on pre-access tests. The factors that could produce false positives among licensee employees and contractors (e.g., administrative errors, medical prescriptions) are equally likely to occur for applicants for unescorted access during pre-access testing. (Note that a change to Section 26.24 will permit licensees to consider any test meeting the Part 26 standards as a pre-access test. Those standards include the appeals process under Section 26.28, and apply to any test that the licensee plans to subsequently use as a pre-access test.) The increased emphasis elsewhere in the rule on detecting subversion must be balanced with measures to prevent errors. If these persons are not provided an appeals process, it is possible that some of them will be effectively barred from the industry based on test results erroneously determined as positive. Providing applicants an opportunity to appeal the validity of the test result will ensure a fair testing process for all persons and enhance program credibility.

The 1995 program performance data presented in NUREG/CR-5758, vol. 6 indicate an industrywide total of 1,112 positive pre-access tests (an average of 10 positive tests per reactor unit). Assuming that 5 percent of these violations are appealed, it is estimated that a total of 56 additional appeals by applicants each year would be required to be processed each year by all licensees. Likewise, measures to detect subversion could increase the number of positive tests by 1,650 each year across the industry. Assuming that 10 percent of these additional violations

are appealed, it is estimated that there would be 165 additional appeals each year from determinations of subversion of the testing process for a total of 221 additional appeals per year, or roughly two appeals per reactor/nuclear fuel facility. The cost of these appeals assumes one hour of MRO review, one hour of staff time for two licensee managers, and one hour of a clerical person's time. It is assumed that one hour of an MRO's time costs \$94.64 per hour, a licensee manager's time costs \$70.71 per hour, and a clerical person's time costs \$33.39 per hour. The estimated cost per appeal is \$269.45 (\$94.64 plus [2 hours x \$70.71 per hour] plus \$33.39). The estimated cost per reactor unit/nuclear fuel facility is \$538.90 (\$269.45 per appeal x 2 appeals per reactor/nuclear fuel facility), or approximately \$500. The total estimated annual industrywide cost of the rule change is \$56,000 (112 reactors/nuclear fuel facilities x \$500 per reactor/nuclear fuel facility).

26.29 Protection of Information

Section 26.29 (b) is revised to permit disclosure of information concerning an FFD violation to a contractor/vendor worker's employer as a companion change to Section 26.23. This change should help contractors and vendors to meet the requirements of Section 26.23 of disclosing information to licensees assigning work to these workers. As pointed out in the discussion under Section 26.23 above, some indeterminate savings would accrue. This section is also revised to allow information concerning an FFD violation to be provided to the presiding officer of an administrative proceeding initiated by a person appealing an FFD violation. The purpose of this revision is to allow disclosure to, for example, state agencies investigating whether the firing of an employee was justified in order to determine unemployment compensation entitlements. This disclosure is to be permissible as long as the subject employee initiated the proceeding. The costs associated with this action will involve some clerical staff time for copying and postage. These costs are not considered significant and will be more than offset by the avoided costs for licensees to request and the NRC to grant an exception to the current disclosure restrictions and by the potential costs of judgments against licensees for not responding to these information requests.

A new Section 26.29 (c) is added to require licensees, upon written request, to provide subject individuals copies of all records pertaining to the determination of a violation of the licensee's FFD policy, e.g., test results, MRO reviews, and management determinations of results pertaining to the individual. Some licensees have interpreted this section in ways that make it difficult for employees to obtain their records. For example, some licensees have allowed employees to see the documents but have not provided them copies of the documents. This is particularly difficult in the case of contractor employees who may no longer reside in the plant area. These actions are contrary to the NRC's intent that persons covered by the rule have

full and convenient access to documents pertaining to employment actions taken under this rule. Staff assumes that half of all individuals determined to be in violation of the licensee's FFD policy may request copies of all records pertaining to that determination (licensees are not required by the rule to provide negative test results to individuals). In 1995 licensees reported a total of 1,467 violations (NUREG/CR-5758, vol. 6), or an average of 13 violations per reactor unit. Assuming that it would take a clerical person one hour with an average wage of \$33.39 per hour to assemble and ship all materials (costs for document copying and mailing are considered negligible), the estimated annual recurring cost per reactor unit/nuclear fuel facility for providing individuals with their records would be \$217.03 (13 tests per year x 50 percent of violators requesting their records x [1.0 hour staff time x \$33.39 per hour]), or approximately \$200. The total estimated annual industrywide cost for the revision would be \$22,400 (112 reactors/nuclear fuel facilities x \$200 per reactor/nuclear fuel facility), or approximately \$22,000.

26.70 Inspections

Clarification regarding the types of documents and records that must be available for audits and inspections has been added to this section. Some instances of contractor and testing laboratory personnel being reluctant to provide documents to NRC inspectors have occurred. No additional costs are anticipated from the rule revision.

26.71 Recordkeeping Requirements

Section 26.71 (b) is revised to clarify that all records relevant to the determination of a violation of the FFD policy must be retained for five years, rather than only records of confirmed positive test results. These records are to include those related to personnel actions following policy violation determinations (such as refusals to test and attempting to subvert the testing process) as well as those pertaining to violations detected during the testing process. This revised wording clarifies licensees' current recordkeeping responsibilities as well as ensure that people covered by the rule would have sufficient access to documentation of personnel actions that can substantially affect their work status. Section 26.71 (c) has also been revised. This section currently requires licensees to retain the records of persons made ineligible for three years or longer until the NRC terminates the license under which the records were created. The revised section now requires that licensees retain for this period records pertaining to FFD policy violations of persons whose authorization to perform Part 26 activities has been revoked. Neither the revisions to Sections 26.71 (b) or (c) are expected to have an appreciable cost impact on licensees.

Section 26.71 (d) is revised to reduce the submission of program performance reports to once a year instead of every six months. This represents a potential cost savings to licensees. The Office of Management and Budget (OMB) reports that, on average, preparing program performance reports requires 40 hours. Assuming that preparing the report requires 40 hours at an average FFD program staff cost of \$50.34 per hour, the savings for each FFD program would be \$2,013.60 (40 hours x \$50.34 per hour), or approximately \$2,000. The total recurring annual industrywide savings from this rule change would be \$148,000 (74 FFD programs x \$2,000 per program).

An additional change requires that licensees provide the number of subversion attempts by type in program performance reports. Although the changes are expected to increase the number of subversion attempts detected, many licensees currently provide information of this type under management actions and lessons learned in the program performance reports; therefore, this change is expected to have no significant cost impact.

26.73 Reporting Requirements

Revisions to Section 26.73 clarify certain reporting requirements. Currently, this section requires licensees to inform the Commission by telephone within 24 hours of significant fitness-for-duty events. The rule provides some examples, but as pointed out in NUREG-1385, item 10.1, significant FFD events are not limited to those examples. Licensees are expected to exercise prudent judgment on whether unusual situations should be reported. The current rule provides four examples of the types of negative acts by licensed operators and supervisors that must be reported to the NRC. One of the revisions adds FFD program personnel as a third class of people whose negative acts would be reportable. This revision makes this section consistent with changes to the rule's scope in Section 26.2 (a). Another revision clarifies that any violation of FFD policy (e.g. refusal to test, possession of illegal drugs) by a member of one of these groups must be reported in contrast to the current requirement to report only confirmed positive test results. This change was necessitated by the use of "positive test result" when "violation of FFD policy" was meant in the original rule.

Clarifications and editorial changes to Section 26.73 (a) (2) (ii) are expected to have no cost impacts. The additional requirements of Section 26.73 (a) (3) through (4) add two new types of significant FFD events to the existing two types of significant events that licensees must currently report. Licensees will be required to report any violation of their FFD policy or any other act that would cast doubt on the integrity of the FFD program, including but not limited to acts that cast doubt on the integrity and honesty of people administering their FFD programs. The second new type of reportable event will be the arrest of a worker for the use, sale, or distribution

of illegal drugs on or off site. These requirements are expected to add two telephone reports per year per site. It is assumed that each telephone report would require one half hour of the FFD manager's time to prepare and report. The estimated annual cost would be \$70.71 (1 hour x \$70.71 per hour), or approximately \$100 per FFD program. The annual industrywide cost of the rule change would be \$7,000 (74 FFD programs x \$100 per program).

26.80 Audits

Section 26.80 will be clarified to require that licensees conduct audits as needed “but no less frequently than every 36 months.” The proposed revision also clarifies that licensees are “responsible for determining the appropriate frequency, scope, and depth of auditing activities within the three-year period based on review of program performance indicators such as the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, previous audit findings, and industry lessons learned.” These changes respond to a petition for rulemaking (PRM-26-1) and will promote performance-based rather than compliance-based audit activities. The audit program will be conducted so that all program elements are adequately covered at least once during the 3-year period. The rule change further clarifies that programs must be audited following a significant change in personnel, procedures, or equipment as soon as reasonably practicable but no later than 12 months after the changes. The NRC recognizes that FFD is an evolving discipline and new issues and problems will continue to arise. In some cases, turnover of FFD program personnel further exacerbates the problems. There is a frequent turnover in the contracted services, such as specimen collections, MRO reviews, and EAP services. Licensee audits have found many problems that were associated in some way with personnel changes and the new personnel not understanding their jobs or the implications of things they did, did not do, or changed. The purpose of these focused audits will be to assure that the change has not adversely affected the operation of the particular program element or function in question. In addition, Section 26.80 (c) will be revised to clarify that the audit report is to identify conditions adverse to the proper performance of the FFD program, the cause of the condition, and recommend corrective actions. The revision also stipulates that management review, follow-up actions, and re-audit of deficient areas must also occur.

One of the clear lessons of the early period of this rule's implementation during 1989 to 1991 was that licensees that performed early pro-active audits of their FFD programs were able to more easily and effectively correct programmatic problems and achieve effective program operations than those that waited the full nominal 12-month period before auditing their programs. Accordingly, this audit requirement will ensure that whatever programmatic problems that may result from significant changes in personnel, procedures, or equipment will be detected and corrected on a timely basis.

The rule change represents a potential cost savings for licensees in certain areas. Information provided by licensees on the length of time for conducting audits of licensee FFD programs varies but is estimated to require approximately two person months, or 320 hours. Although the rule change could conceivably reduce the frequency of licensee audits to once every three years, this is unlikely due to significant changes to licensee programs that would require auditing following the changes, testing errors or other administrative problems that would trigger an audit, and particular audit policies and practices established by licensee management. Therefore, a more realistic audit frequency would be once every two years on average. This would represent a fifty percent savings to licensees in FFD program audit costs, or an estimated 160 hours of staff time annually. Assuming an average FFD program staff labor cost of \$50.34 per hour, the annual estimated cost savings of this rule change would be \$8,054.40 (160 hours x \$50.34 per hour).

There would, however, be additional costs associated with reviewing program performance data for the purpose of determining audit frequency. It is assumed that licensees are already compiling most if not all of the program indicators of the types referenced above. It is further assumed that licensees would review these data annually when submitting program performance reports for the purposes of determining audit frequency. It is estimated that the FFD manager, an operations manager, and a quality assurance manager would review FFD program performance data to determine audit frequency. It is assumed that each person would spend four hours reviewing the data at an average cost of \$70.71 per hour. It is further assumed that each manager would spend one hour collectively deciding audit frequency based on the data, and making a written record of the basis of that decision. The estimated cost of this action would be 15 hours of managerial staff time plus one hour clerical staff time, which is \$1,094.04 (15 hours x \$70.71 per hour plus one hour x \$33.39 per hour).

The net savings of the rule revision would be \$6,960.36 per FFD program (\$8,054.40 minus \$1,094.04) or approximately \$7,000 per FFD program. The estimated annual industrywide savings of the rule change would be \$518,000 (74 FFD programs x \$7,000 per program).

Further, as described in Section 2.7 (n) of the Appendix to Part 26, licensees must still continue to audit contract HHS-certified laboratories annually. Licensee audits of the HHS-certified laboratories continue to find problems related to turnover and new personnel. In one case, the licensee's auditors had found sufficient problems in the first part of an audit to issue a stop-work order. The laboratory subsequently lost its HHS certification. Therefore, based on experiences gained to date, the NRC continues to believe that licensees must continue to audit at least annually the quality of contractor- or vendor- performed program elements, particularly when such activities are provided off site or are not under the direct, daily supervision of the licensee.

Another change Section 2.7 (n) states that licensee audits of HHS-certified laboratories “must include review of inspection reports made under the HHS-certification program but need not duplicate areas covered by the HHS inspection.” This rule change should eliminate redundancy between licensee and HHS inspections, resulting in a potential cost savings to licensees. A typical licensee audit of the HHS-certified laboratory currently takes three days and requires three people. The revision will cut this work by half (12 hours staff time) for one person at sites using HHS cutoff levels and by one third (8 hours staff time) for one person at those sites using lower cutoffs and testing for additional drugs. It is assumed that two thirds of the licensees (50 programs) would reduce their staff costs by 12 hours, and the remaining licensees (24 programs) would reduce their audit time by eight hours. Assuming an average FFD program staff labor cost of \$50.34 per hour, the annual estimated cost savings of the rule change would be \$604.08 (12 hours x \$50.34 per hour) and \$402.72 (8 hours x \$50.34 per hour), or approximately \$600 and \$400, respectively. The estimated annual industrywide savings of the rule change would be \$49,600 ([50 FFD programs x \$600 per program] plus [24 programs x \$400]) or approximately \$40,000.

26.90 Enforcement

There are no changes to this section.

Appendix A--Guidelines for Drug and Alcohol Testing Programs

1.1 Applicability

There are minor editorial changes to this section. No cost impact on licensees is expected from these changes.

1.2 Definitions

Changes to this section include deletions of defined terms that are either redundant with definitions in Section 26.3 or are clear in the context of this Appendix. A revision defines "limit of detection" (LOD), which is now used in the rule. Another revision deletes the definition of “permanent record book.” This revision will make the Appendix consistent with recent amendments to the HHS Mandatory Guidelines and the Department of Transportation FFD regulations which eliminated the requirement for a permanent record book. Because HHS will no longer require a permanent record book, requirements for a permanent record book are removed

throughout the rule. The permanent record book was originally required based on the belief that such a book was necessary to ensure that critical information regarding collection and testing of each individual specimen was recorded. However, the NRC's FFD drug testing program requires all information on individual tests to be recorded on the chain-of-custody form and other forms and requires that all information related to determining violations be retained for five years. Therefore, the permanent record book is redundant and there is no compelling need to maintain a separate longstanding record book. Eliminating this requirement reduces the regulatory burden on licensees and increases the efficiency of licensee drug testing programs (because the time taken to enter information into the record book while the person being tested and is waiting is eliminated). The elimination of this requirement does not preclude licensees from making their own determination of the advantages of the use of a permanent record book and deciding to continue to maintain one, and the NRC encourages licensees to consult their legal staffs regarding the advantages of continuing to use a permanent record book. This should reduce the regulatory burden on licensees; the cost savings are calculated in Section 2.4(g).

2.1 The Substances

Amendments to this section note that return-to-duty testing is one of the types of testing that licensees must conduct; clarify that licensees may test for substances suspected of having been abused, including prescription drugs; and clarify that licensees may consider any detected drugs or metabolites when determining appropriate action to be taken. The NRC deems it appropriate, in these particular instances where reasonable suspicion of an FFD problem exists, to allow close scrutiny at the discretion of the licensee. The licensee continues to be responsible for assuring that the results establish a valid basis for any action taken. Revisions to this section should have no cost impacts on licensees.

2.2 General Administration of Testing

Several editorial changes to this section should have no cost impact on licensees. In addition, this section currently requires licensees to retain all custody-and-control forms as a permanent record. In a related revision, the form currently termed "chain-of-custody" is changed to "custody-and -control" as the new way to refer to these forms. Licensees recently pointed out that they have started to accumulate an appreciable volume of files. Revisions establish a reasonable schedule for disposition of the chain-of-custody forms. The retention of supporting records related to determinations of violations of FFD policy for five years would provide appropriate records for responding to background investigation inquiries while reducing the storage burden on licensees. In addition, licensees will be allowed to destroy custody-and-

control forms for negative test results after recording appropriate summary information for program administration purposes. The clarification will establish disposition schedules that permit prompt destruction of forms with negative test results and appropriate retention for positive results and matters under legal proceedings. This may provide licensees savings in administration and recordkeeping costs. In 1995 a total of 150,121 tests were administered by licensees, with 1,476 positive test results and 148,645 negative test results. On average, there were 2,065 negative test results at each FFD program. It is assumed that the revision would save an estimated 10 minutes per negative specimen in custody-and-control processing time, recordkeeping, and administration. This would save 344 hours of clerical staff time, or \$11,486.16 (344 hours x \$33.39 per hour), or approximately \$11,500 per licensee program. The total estimated annual industrywide cost savings would be \$851,000 (74 FFD programs x \$11,500 per program).

2.3 Preventing Subversion of Testing

There are several editorial changes to this section. One revision relaxes the frequency of appropriate background checks and psychological evaluations of FFD program personnel from at least once every three years to at least once every five years. This change was made in response to licensee experience and for consistency with the frequency of re-investigations under generally accepted practices for obtaining security clearance from Federal agencies. Reducing the frequency of background checks of FFD personnel from once every three years to once every five years should provide a small savings to licensees. On average, there are six people per FFD program. Attrition of personnel would reduce the number of people who work in programs for more than three years. This would reduce the number of re-evaluations. It is estimated that an average of 2.5 background evaluations are conducted annually. The rule change would reduce this to 1.5 background evaluation annually, or a savings of 1 evaluation per year. It is assumed that a background evaluation involves two hours of professional time at \$50.05 per hour and one half hour clerical staff time at \$33.39 per hour. The estimated savings would be \$116.80 (2 hours x \$50.05 per hour plus .5 hour x \$33.39 per hour), or approximately \$100 per FFD program. The estimated annual industrywide savings would be \$7,400 (74 FFD programs x \$100 per program), or approximately \$7,000.

Other revisions note the explicit inclusion of FFD program personnel in the licensee's testing program. These revisions are addressed in Section 26.2 of the rulemaking.

2.4 Specimen Collection Procedures

Revisions to Section 2.4 (d) address a significant legal issue which could have an impact on all urinalysis test results. This revision indicates that the signature of the transportation courier does not have to be included in the custody-and-control form because the specimens and the forms are sealed in tamper-evident containers during transit to the laboratory, and couriers, express carriers, and postal service personnel do not have access to the custody-and-control forms. This is in keeping with standard forensic laboratory procedures, and should streamline the specimen transportation process. It is also consistent with 1994 changes to the HHS Mandatory Guidelines and DOT regulations. These changes codify the result of a Federal appeals court decision which determined that a courier's signature on the chain-of-custody form was not necessary (*Interstate Brands Corp. v. Local 441 Retail, Wholesale and Department Store Union*, 11th Circuit U.S. Court of Appeals, No. 94-6306, Dec. 14, 1994). This change is expected to provide a potentially significant but indeterminate savings to licensees and the NRC staff.

Revisions to Section 2.4 (f) will clarify the privacy requirements for urine specimen collection in the event of suspected subversion. The revision clarifies that a person who presents a specimen that fails to meet acceptable standards or is of questionable validity would constitute a reason to believe that the person may try to subvert the testing process. This revision also clarifies the privacy requirements for testing. It is intended to ensure that privacy is maintained unless there is reasonable cause to suspect subversion. In particular, the revision makes clear that questionable specimens that have been determined through MRO review and special processing not to be a violation of FFD policy should not compromise the employee's privacy at a later specimen collection. The conditions which warrant a subsequent observed specimen collection are further clarified in a revision to Section 2.4(f)(2). The change stipulates that a variation in an employee's oral temperature by more than 1°C/1.8°F from the temperature of the specimen is grounds for requiring an observed specimen at a later time. The revisions to Section 2.4 (f) would have no cost impact on licensees. The change to Section 2.4(f)(1) should in some instances produce a minimal reduction in burden by reducing the incidence of observed specimen collection.

Section 2.4 (g) (4) is revised to eliminate the current requirement that employees to be tested list prescription medications and over-the-counter (OTC) preparations taken or administered in the past 30 days. The availability of such information does not eliminate the need to do a confirmatory test on an unconfirmed positive screen test result. This information becomes useful only at the point at which the MRO reviews a confirmed positive test result. It is at this stage, when this information can be conveyed by the tested individual directly and confidentially to the MRO, that information about medications the person may be using or has

used becomes germane to determining whether a fitness-for-duty policy violation has occurred. Eliminating the opportunity for the tested individual to provide this information on the chain-of-custody form should enhance the individual's privacy interests by precluding the chance of any testing program or licensee personnel other than the MRO learning of the individual's use of medication. Eliminating the requirement to list prescription medications or OTC preparations may provide a small cost savings to licensees. However, it is assumed that many people are not using these drugs and that those who do could recall their use in a very short (less than 1 minute) period of time. Therefore no cost savings have been estimated.

All references to the requirement for a permanent record book are deleted from the specimen collection procedures in Section 2.4 (g) (9), (14) (formerly [g] [15]), and (23). The permanent record book was originally required based on the belief that such a book was necessary to ensure that critical information regarding collection and testing of each individual specimen was recorded. However, the NRC's FFD drug testing program requires all information on individual tests to be recorded on the custody-and-control form and other forms and requires that all information related to determining violations be retained for five years. Therefore, the permanent record book is redundant and there is no compelling need to maintain a separate longstanding record book. Eliminating this requirement reduces the regulatory burden on licensees and increases the efficiency of licensee drug testing programs (because the time taken to enter information into the record book while the person being tested and is waiting is eliminated). Both HHS and DOT have eliminated the requirement for a permanent record book. The elimination of this requirement does not preclude licensees from making their own determination of the advantages of using a record book and deciding to continue to maintain one. It is assumed that this change would save an average of two minutes of FFD staff time per test. In 1995 there were an average of 2,085 tests per FFD program. The total cost savings would be an estimated \$2,088.54 per FFD program ($\$33.39 \text{ per hour} \times .03 \text{ hours} \times 2,085 \text{ tests}$), or approximately \$2,100. The total estimated annual industrywide savings would be \$155,400 ($74 \text{ FFD programs} \times \$2,100 \text{ per program}$), or approximately \$155,000.

An amendment to section 2.4 (g) (10) will allow licensees to have an individual, other than a collection site person, accompany an individual into a rest room not in the designated collection site if the designated collection site is inaccessible. Amendments to sections 2.4 (g) (15) and 2.4 (g) (24) allow licensees to have an individual, other than a collection site person, observe the collection of a specimen whenever there is reason to believe the individual may have altered or substituted the specimen. The requirement that the individual be of the same gender as the employee still exists, however. This change is based on NRC's belief that it is not always possible, under all circumstances, to have a collection site person of the same gender available, and these revisions are consistent with HHS Mandatory Guidelines. This should reduce the regulatory burden on licensees. However, staff expects only minimal savings (if any) due to the

relatively infrequent and unpredictable instances when a non-collection site person would be needed. Therefore, no cost savings have been estimated.

Revisions to Section 2.4 (g) (11) of the rulemaking are intended to provide licensees flexibility in determining the amount of a urine specimen to be collected and may represent a potential cost savings in reduced time needed in some cases to collect an adequate amount of specimen. Currently, the section requires licensees to collect at least 60 milliliters (ml) from the tested person. Two or more successive voids can be combined to reach this amount. Under the revision, 30 milliliters (ml) of urine will be needed for testing at the HHS-certified laboratory, and an additional amount would be needed for any on-site testing and testing for additional drugs. The total amount must be predetermined by each licensee. This revision will likely further reduce the number of cases where the person cannot produce an adequate specimen. It is assumed that very few (an estimated five percent) of people being tested would produce less than 60 ml, an amount that should be sufficient in most cases to allow for both HHS-certified laboratory testing and any necessary additional drug testing. The NRC understands that laboratories require only a few milliliters for testing and that a 30 ml sample is sufficient in volume for both immediate testing and the retention of a second aliquot for further testing, if necessary. The NRC also understands that accurate measurement of specimen temperature is difficult with a small volume but does not believe that "partial" specimens should be disposed of and not tested. It is assumed that half of these people (or 2.5 percent) would provide less than 60 ml but an amount over 30 ml that is sufficient for testing purposes.

Eliminating the waiting period for those people who do provide an amount over 30 ml but less than 60 ml should provide a cost savings. It is estimated that this would save an average of 30 minutes waiting time for 2.5 percent of the total annual number of tests. In 1995 a total of 150,121 tests were conducted, or an average of 2,085 tests per FFD program. 2.5 percent of these tests is 52 tests. Assuming an average time savings of 30 minutes at an average utility rate of \$44.78, the total staff time savings would be \$1,164.28 (52 tests x 0.5 hours x \$44.78 per hour), or approximately \$1,200 per program. The total industrywide savings would be \$88,800 (\$1,200 per FFD program x 74 FFD programs), or approximately \$89,000.

However, the revised Section 2.4 (g) (11) will also stipulate that partial specimens are not to be combined in one container. This revision could represent potential costs to licensees. The current rule states that if a person produces less than the required amount of urine, additional urine is to be collected in separate containers until the total required amount has been collected. The partial specimens are then to be combined into one container. The intent of the rule revision to Section 2.4 (g) (11) is to avoid potential problems that could be created by combining specimens, a practice that increases the possibility of contamination or error. One specimen, usually the first one, may be suspected of being adulterated or substituted and

combining it with the second specimen would dilute the first. In addition, combining specimens would lower the concentration in any drugs in the first specimen, since liquids may be given to the donor before he or she provides the second specimen. To avoid these problems, this section is revised to stipulate that in cases where the specimen volume is insufficient to fulfill the HHS-certified laboratory testing requirements, and an additional void is required, the primary specimen and all subsequent specimens are to be kept in separate containers. This new requirement could result in some additional cost to licensees. It is conservatively assumed that five percent of the people who are tested would not be able to provide a sample of sufficient quantity in the first void. In such cases, it is assumed that an average of 2.5 voids per person will be necessary to provide an acceptable specimen, that is a sample of sufficient volume for both immediate testing and the retention of a second aliquot for further testing, if necessary. In 1995, a total of 150,121 tests were conducted, or an average of 2,085 tests per FFD program. Five percent of these tests is 104 tests per FFD program. The rule change would result in an average of 156 $[(104 \times 2.5) - 104]$ additional specimens per FFD program and a total of 161 additional tests $[(156 \times .03 \text{ blinds}) + 156]$. Assuming an average test cost of \$50 per test, the estimated total cost of the rule revision for each licensee would be \$8,050 $(161 \times \$50)$. This cost estimate is conservative, particularly for licensees with on-site testing facilities. The \$50 average test cost applies to off-site testing at a HHS-certified laboratory and includes shipping costs. However this average test cost was used to calculate additional testing costs for licensees with on-site laboratories as well. The cost effect of this rule change results from the small portion of people who have difficulty providing a specimen of sufficient volume. The revised rule stipulates, in order of priority, how the available specimen should be tested. The specimen volume provided first must be used for testing of the specimen at the HHS-certified laboratory and second for provision of a split specimen. Lastly, if sufficient volume is available, on-site screening tests are to be conducted. The NRC is aware that some donors who provide multiple voids at facilities that test on-site may produce sufficient specimen volume to permit testing on-site, as well as provide sufficient quantity of specimen for the first two testing requirements. However, the number of such donors is not readily quantifiable. Given the testing parameters stated in the revised rule, staff has made a conservative cost assessment by applying the \$50 per test cost to all FFD programs. The total industry cost of the revision would be \$595,700 $(74 \text{ FFD programs} \times \$8,050)$ or approximately \$596,000.

Section 2.4 (g) (14) will provide clearer guidance for examining specimens for clarity and meeting other acceptability criteria. The section provides clearer procedures if the specimen is not acceptable. Urine color and clarity are affected by a wide range of physiological changes including an individual's health, level of hydration, medications, and diet. Test personnel should therefore use observation of color and clarity of the specimen only for gross signs of adulteration. These changes are expected to have no cost impact on licensees.

Revisions to Section 2.4 (g) (18) will eliminate the second breath test specimen requirement when the first specimen is negative. The licensee may, at its discretion, collect and measure the breath a second time. This change reduces the impact on individuals being tested and on the licensee by reducing the amount of time taken by the testing process. It has been determined that the second test after a negative result in the current required testing process is not technically necessary and can be modified.

This change should create a significant potential cost saving to licensees. The current procedure requires the subject individual to provide the first breath specimen, wait no less than 2 minutes and no more than 10 minutes, then provide the second specimen. Eliminating the second procedure should save licensees an estimated 10 minutes from each test procedure, including the time between testing and the time to take the second test. There may be instances where no alcohol is present but the evidential grade equipment results in a reading higher than 0.01 percent BAC due to acetone or other chemical interference, requiring a second test (for instance, if a maintenance worker being tested had acetone on his clothing when reporting for testing). However, it is reported that evidential grade breath analysis is generally free of interference at 0.02 percent BAC, and interference from other chemicals is unlikely at 0.01 percent.³⁷ It is estimated that, on average, each reactor unit administered 1,365 tests to subject individuals in 1995 (150,121 total tests at 110 reactor units), and that two alcohol tests had to be confirmed because the initial result was positive (in 1995, 265 tests were confirmed positive for alcohol, or an average of three confirmed positive tests per reactor unit). Assuming an average utility labor rate of \$44.78 per hour, the estimated staff time labor savings would be the total number of tests multiplied by the average utility wage rate labor time. The estimated potential cost saving would be \$10,375.97 (1,365 tests minus three tests x [\$44.78 per hour x .17 hourly savings per test]), or approximately \$10,400. The total estimated industrywide savings would be \$1,164,800 (\$10,400 per reactor/nuclear fuel facility x 112 nuclear reactors/nuclear fuel facilities), or approximately \$1,165,000.

Revisions to Section 2.4 (g) (19) regarding alcohol testing have already been addressed in Section 26.24 of the rule. Editorial revisions to Section 2.4 (g) (20), (23), (24), (25), and (27) are expected to have no cost impact on licensees.

Revisions to Section 2.4 (i) will require licensees to send specimens to the HHS-certified laboratory as soon as reasonably possible, or take appropriate and prudent steps to assure that specimen degradation does not occur. Except under unusual circumstances, the time between specimen collection and receipt by the HHS-certified laboratory should not exceed 48 hours or the time from collection to screening test exceed 72 hours. Collected urine specimens will

³⁷Arthur Zebelman, Laboratory of Pathology, Seattle, Washington, personal communication, 1994.

continue to have to be shipped to the HHS-certified laboratory or cooled to not more than 6 degrees centigrade (42.8° F) within 6 hours of collection as previously required by Section 2.7 (c). The rule changes also clarify specimen packaging requirements. These revisions are part of several changes throughout the rule which are intended to address the possibility that specimens can become degraded between the time they are collected and the time they are screened and confirmation tested. Reports from several licensees have suggested that specimen degradation during shipment has been the cause of “false negative” test results. The NRC has been advised that specimens not kept chilled during storage or transit may have become contaminated because of the buildup of bacteria and their wastes to an extent sufficient to possibly alter laboratory test results. Pilot tests conducted by the NRC detected a significant level of cocaine metabolite deterioration when urine specimens with a high relative acidity/alkalinity (pH) level were stored at relatively high temperatures (i.e., 100° F) for 36 hours or more. A modest study by one licensee showed a definite decrease in the concentration levels of THC in specimen bottles stored at room temperature for one week (e.g., from 199 to 178 ng/ml); where the specimen was allowed to touch the inside of the cap sealer the concentration was reduced more than one half (e.g., from 199 to 77.8 ng/ml). Also, the reasons for unsatisfactory results of blind performance tests reported by the HHS-certified laboratories are that the blind specimens degraded below the cut-off levels or that the specimen containers adsorbed some of the drugs or metabolites.

Currently shipping companies such as DHL, Federal Express, and UPS have strict packaging and shipping requirements for biological specimens that meet or exceed the revisions. Therefore, for licensees using these services no additional cost impact is expected. Although it is common practice to use courier or express service, it is likely that some licensees would be required to switch from their use of normal postal delivery to such services or revise their shipping procedures to comply with the changes. It is assumed that 20 percent of licensees would incur additional cost impacts as a result of the rule change. It is estimated that 27 FFD programs conduct on-site testing, and therefore five (approximately 20 percent) of these sites would be required to revise their shipping procedures. It is assumed that ten of the remaining 47 sites (approximately 20 percent) that send all specimens off-site would be required to revise their shipping procedures. It is estimated that the five FFD programs with on-site testing programs would be required to send an estimated average of 237 specimens³⁸ for off-site testing ([2,085 collected specimens x 0.98 percent positive rate plus 10 percent of negative screens plus three

³⁸Revisions to Section 2.8 (e) (2) reduce the number of blind performance test specimens that licensees are required to submit for analysis as part of their FFD quality assurance and quality control program. After the initial 90-day period, the minimum number of blind performance test specimens will be lowered from 10 percent of all samples submitted to 3 percent, or 10 blind performance specimens, whichever is greater. In estimating licensee costs that result from changing shipping procedures in order to comply with revisions to Section 2.4(i), the greater number of 10 (as opposed to 3 percent) is used a conservative cost estimate.

percent blind performance tests] which equals 20 plus 207 plus 10 = 237). It is estimated that the ten FFD programs sending all specimens off-site would be required to send an estimated average of 2,148 specimens off-site (2,148 collected specimens plus 63 blind performance specimens) under revised shipping procedures. It costs approximately \$6 to \$8 to send up to 3 or 4 biological specimens via overnight delivery or express.³⁹ Assuming that costs associated with implementing the revised specimen shipping procedures would add, on average, \$5 more per specimen, the estimated cost for licensees with on-site testing facilities affected by the rule change would be \$1,185.00 (237 specimens x \$5.00 per specimen), or approximately \$1,200. The estimated cost for licensees sending all specimens for off-site testing affected by the rule change would be \$10,740.00 (2,148 specimens x \$5.00 per specimen), or approximately \$10,700. The total estimated annual industrywide cost for this requirement would be \$113,000 (5 programs x \$1,200 per program plus 10 programs x \$10,700 per program).

Other revisions to Section 2.4 (i) will provide guidance on the use of shipping documents for documenting custody and control of specimens during shipment; the guidance would conform to changes to Section 2.4 (d) in adopting recent changes to HHS Mandatory Guidelines to address a significant legal issue. Staff expects no costs from the change due to the fact that the revision would entail few, if any, changes to current practice. Any potential cost savings would arise from reducing the chance for any legal action stemming from charges of insufficient custody. These changes were made to assure that specimens are not tampered with during shipment.

Revisions to Section 2.4 (j) clarify that collection personnel should report incidents when an individual refuses to cooperate in the testing process to appropriate management, as designated by the licensee, rather than through the MRO to appropriate management. The NRC believes the MROs need not be a key player because refusals to cooperate should be administrative concerns (policy violations) rather than medical problems. This flexibility in internal reporting and decision making is expected to provide an indeterminate savings.

2.5 HHS-Certified Laboratory Personnel

No changes in this section are expected to have a cost impact.

³⁹Arthur Zebelman, Laboratory of Pathology, Seattle, Washington, personal communication, 1994.

2.6 Licensee Testing Facility Personnel

No changes in this section are expected to have a cost impact.

2.7 Laboratory and Testing Facility Analysis Procedures

Revisions to Section 2.7 (c) clarify that the current requirement to refrigerate specimens not shipped within 6 hours of collection. This revision conforms to the change to Section 2.4 (i) and is expected to have no cost impact on licensees. Revisions to Section 2.7 (c) will also allow means other than refrigeration to keep specimens in a chilled state and contingency measures to be used rather than require emergency power equipment to maintain specimens in a chilled state. This should ease the regulatory burden on licensees and provide flexibility in the future but would result in minimal savings due to the infrequency of prolonged power failures and the extensive contingency measures (e.g., emergency power equipment) licensees already have in place.

Revisions to Section 2.7 (d) will clarify that the MRO must report subversion of the testing process to management and such acts must be treated as a violation of FFD policy. Another change adds urine specimens that are questionable for adulteration or dilution to those specimens that licensees conducting on-site testing must ship to an HHS-certified laboratory for testing. A new Section 2.7 (e) will also indicate that, in order to use the cut-off levels specified in the rule, the specimen must be valid, and if the specimen is significantly diluted, testing need not be conducted. A related revision to Section 2.7 (i) (formerly [h]) adds all specimens that have been adulterated or diluted, or that have been associated with personnel actions for any other reasons, to specimens that must be kept in long-term frozen storage for at least one year by HHS-certified laboratories. The NRC understands that most licensees and their HHS-certified laboratories are currently doing these actions. Therefore, no additional cost impacts from these revisions are expected.

The new Section 2.7 (e) will require that specimens be tested to determine their validity and detect evidence of adulteration or dilution to reduce the potential for subversion of the testing process. Licensees have encountered subversion of the testing process by substance abusers to avoid detection and the NRC desires to minimize the vulnerabilities in the testing process that have been exploited. Licensees conducting onsite testing will be required to determine the validity of all specimens collected by testing for creatinine, pH, and nitrites. These licensees will be required to send any specimens that do not meet specifications for normal screening testing to their HHS-certified laboratory for further testing. HHS-certified laboratories will be required to

test for validity these questionable specimens received from licensees testing on site and all specimens received from all other licensee programs. At a minimum, this testing is to include analysis for creatinine, pH, and nitrites. If a specimen's creatinine concentration is found to be less than 20 milligrams per deciliter, the laboratory would have to measure the specimen's specific gravity.

This new Section 2.7 (e) will also require those specimens found to be of questionable validity to be subject to special processing at the HHS-certified laboratory. This testing is to consist of screen testing in which the laboratory would use FDA-approved analytical kits having the lowest concentration levels marketed for the particular screening technology(ies) the laboratory is using. When the screening testing detects the presence of one or more proscribed drugs, the HHS-certified laboratory would be required to test for the drug(s) using GC/MS at the laboratory's limit of detection (LOD). Negative screening results from this special processing is also to be subject to GC/MS testing at the laboratory's LOD if the MRO's review indicates the need for more information. Because not all dilute specimens are the result of attempted subversion, testing at low concentration levels and at LOD should minimize incorrect determinations and reduce the potential for unnecessary second observed collections.

Although the staff is aware that several licensees currently measure SG or other parameters as a means of determining specimen validity, it is conservatively assumed that all licensees would have to newly implement the new specimen validity testing requirement. The staff is also aware that there is currently on the market at least one test strip that is designed for inexpensive, rapid analysis of creatinine, pH, and nitrite to detect specimen adulteration and dilution. These test strips are designed for reliable validity testing at on-site drug testing facilities and collection sites. The 27 programs that test on site can use these test strips to test for specimen validity. The cost per specimen for labor and materials is an estimated \$1.00. This amount would cover the cost of the test strip, quality control materials, and a collection site person's time to process the specimen. It is estimated that each FFD program conducts an average of 2,085 tests annually. Therefore, each of the 27 programs that tests on site would have an annual added cost of \$2,085 (2,085 specimens x \$1.00 per test), or approximately \$2,100, for validity testing at the site.

Under the new Section 2.7 (e) the on-site testing programs will be required to send any specimens found not to meet the specifications for normal screening testing to an HHS-certified laboratory for additional validity testing and, if necessary, special screening and confirmatory

testing. Research data indicate that 10 percent of specimens tested for validity will be determined to not meet those specifications.⁴⁰

Under this assumption, each of the 27 programs that tests on site would send 209 specimens (2,085 specimens x 10 percent) per year to its HHS-certified laboratory for additional validity testing.

Whatever costs that these licensees may incur for this additional validity testing will be largely determined by the validity testing procedures already in place at the HHS-certified laboratories. HHS has recently adopted its National Laboratory Certification Program (NLCP) Program Document #35 which recommends that the laboratories it certifies test for validity, in a manner similar to that required by this change to Section 2.7 (e), all specimens received from HHS and Department of Transportation testing programs. By the time NRC licensee FFD programs are required to have their specimens tested for validity at HHS-certified laboratories, the laboratories can be expected to have achieved a low-cost, automated routine for testing all specimens for validity. That being the case, the staff assumes that the HHS-certified laboratories will be able to very inexpensively analyze specimens for creatinine, pH, nitrites and, if necessary, specific gravity. It is also reasonable to expect that, to keep costs down by maintaining normal operations, the laboratories will test for validity specimens sent by NRC licensees even if the Commission does not mandate such testing. Some HHS-certified laboratories, in fact, have indicated that testing for adulteration and dilution would be considered a cost of doing business that would not be passed on to their customers. One laboratory, on the other hand, has speculated that it may charge up to \$1 per specimen for such testing. Given the competition among drug testing HHS-certified laboratories, however, it is very likely that very few, if any, laboratories will charge any additional cost for this relatively simple, automated validity testing. The staff, therefore, assumes that this rule revision will create no new costs for licensees for such testing.

Based on this information, the staff assumes that each of the 27 programs that tests on site would have a total added annual cost for validity testing of \$2,100 per program. Therefore, the total annually recurring cost for validity testing for these 27 programs that test on site would be approximately \$56,700 (27 programs x \$2,100 per program).

⁴⁰For example, findings from two studies indicate that some proportion of donors are using hydration to avoid drug use detection. A study by the National Laboratory Certification Program (NLCP) examined 10,000 specimens randomly selected from Department of Transportation-regulated screening programs. Of these specimens, 7.6 percent were found to be dilute, using HHS standards. The 758 dilute specimens were further analyzed; of these, 10 percent were positive using HHS cut-off levels. Therefore, it is expected that up to 10 percent of dilute specimens may contain traces of proscribed drugs (Drug Detection Report, September 8, 1992; MRO Newsletter, 2 (1), 1993.

The 47 programs that do not test on site currently send on average 2,085 specimens to their HHS-certified laboratories for testing. As noted above, the new Section 2.7 (e) will require these licensees to have their laboratories first test all these specimens for validity. Assuming that HHS-certified laboratories will absorb the costs of such testing, as discussed above, this testing should create no new costs for these licensees. Therefore, the industry-wide annually recurring cost for validity testing would amount to \$56,700.

The new special screening and confirmatory testing requirements could also result in potential increased costs. As stated above, each FFD program conducts an average of 2,085 tests annually and data indicate that approximately 10 percent of all specimens fail to meet the specifications for normal screening testing. The staff assumes that up to 2 percent of all specimens may require special processing because they will be determined to be of questionable validity. (These same and other data from various sources lead the staff to estimate that, of the total number of specimens that are determined to not meet specifications for normal screening testing, approximately 40 percent [or 4 percent of all specimens] will be found to be invalid due to adulteration or dilution. These specimens will receive no further testing. Likewise, 40 percent [or 4 percent of all specimens] will be found to be valid and, therefore, will be processed with normal screening and, if necessary, normal confirmatory testing. This leaves 20 percent [or 2 percent of all specimens] that will be determined to be of questionable validity and, therefore, will be subject to special processing at HHS-certified laboratories under the Section 2.7 (e) requirements.) The staff is aware that, although the costs of confirmatory tests vary across the industry, a majority of licensees are already obtaining limit-of-detection testing services as part of their laboratory services free of extra charge. Just as with validity testing, the staff expects that the competitive nature of the drug testing business will force HHS-certified laboratories to establish relatively inexpensive, automated procedures for special processing of specimens along the lines called for in the Section 2.7 (e). The staff, therefore, assumes that the Section 2.7 (e) special processing requirements will create no new costs for licensees.

In addition to the costs for validity testing discussed above, the 27 FFD programs that test on site will likely incur additional costs for having to send a few additional blind performance test specimens to their HHS-certified laboratories in conjunction with the 209 specimens sent off site for special processing. Additional blind performance specimens equal to 3 percent of the total number of additional specimens at \$65 specimen would result in an annually recurring cost impact of \$408 ($[209 \times .03]$ specimens \times \$65 per specimen), or approximately \$400, at each of these 27 FFD programs.

However, the industry's additional costs for validity testing and blind performance test specimens should be offset by the savings derived from eliminating the need to collect, under observed conditions, and test a second specimen in cases in which this is currently required.

The specimen validity testing and special processing eliminates the need to collect and test a second specimen in most cases. The cost savings realized from the reduction in the need for collecting second specimens would be an estimated \$9,359.02 (209 tests x \$44.78 per hour) per FFD program (both at the 27 programs that test on site and the 47 programs that do not test on site) resulting from a one-hour labor savings for not having to recollect specimens. There would also be some minor cost savings associated with eliminating the FFD program staff time needed to conduct a second observed specimen collection, but these savings are considered insignificant. The savings associated with not testing a second specimen are estimated to be \$10,450.00 (209 tests x \$50.00 per test). The total estimated savings for each of the 74 FFD program resulting from requiring validity testing and special processing instead of requiring a second, observed specimen collection and testing would be \$19,809.02 (\$9,359.02 + \$10,450) or approximately \$19,800.

In summary, each of the 27 FFD programs that test specimens on site would incur a total of \$2,500 in additional annually recurring costs due to this new Section 2.7 (e) (\$2,100 for validity testing and \$400 for additional blind performance specimens). The total added costs for these programs would be \$67,500 (\$2,500 x 27 programs). These additional costs would be more than offset by an annually recurring savings of \$19,800 for each program by eliminating the need to collect, under observed conditions, and test a second specimens in some circumstances. The total savings for these programs would be \$534,600 (\$19,800 x 27 programs). These programs' annual net savings would be \$17,300 on an individual basis (\$19,800 in savings minus \$2,500 in costs) and \$467,100 (\$17,300 x 27 programs) on a collective basis.

Each of the 47 programs that do not test on site would incur no additional costs due to Section 2.7 (e). Instead, they would benefit from annually recurring savings of \$19,800 for each program by eliminating the need to collect, under observed conditions, and test a second specimens in some circumstances. These 47 programs' total savings would be \$930,600 (\$19,800 x 47 programs). Therefore, the total industry-wide net savings would be \$1,397,700.

In section 2.7 (f) (formerly 2.7 [e]) a minor administrative edit clarifies that only positive GC/MS opiate tests need be tested for 6-AM (a metabolite specific for heroin). A revision to Section 2.7 (f) (1) would clarify that non-instrumented immunoassay testing devices are not to be used in NRC regulated FFD programs, pending HHS review and approval. These revisions are expected to have no cost impact on licensees.

A new Section 2.7 (f) (3) permits multiple screening tests in certain limited situations. This revision adopts a 1994 change HHS made to its guidelines. The change is intended to apply primarily to amphetamines to reduce the effect of possible cross reactivity due to structural analogs. Licensees and the NRC staff have expressed concern that the use of multiple screening tests not be used on a routine basis because of the increased number of false negative test results that could occur. No costs or savings should result from this provision.

Revisions to Sections 2.7 (f) (formerly 2.7 [e]) and 2.7 (g) (2) (formerly 2.7 [f] [2]) will explicitly allow licensees using lower cut-off levels to conduct only the more stringent test and calculate the number of positive test results that would have occurred using the NRC cut-off level. This clarifies the original intent of the rule and is expected to have no cost impact on licensees. In some cases, the rule change may represent potential cost savings to licensees that currently test at both cut-off levels, but the cost savings to the industry would be insignificant. Another revision to Section 2.7(g)(2) would require licensees to test for 6-acetylmorphine (6-AM) when the morphine concentration found in confirmatory testing exceeds 2,000 ng/ml. This revision would adopt a change the HHS recently made to its Mandatory Guidelines. Since it is a reduction from the current requirement that all specimens presumptively positive for morphine must be GC/MS tested for 6-AM, this revision is expected to produce a significant, but unquantifiable savings.

A new Section 2.7 (g) (6) will require licensees to test for d and l isomers of amphetamines. Some legal drugs (e.g., Vicks® inhaler) contain amphetamine compounds that may yield a laboratory-confirmed positive for amphetamine use. Laboratory confirmatory tests for the d and l isomers are able to differentiate between compounds and to identify those positive test results that are the result of legal use. Many licensees have already been using this test as further confirmation of positive test results for amphetamines. These tests are currently suggested by a technical advisory issued by HHS to HHS-certified laboratories. Thus, these confirmatory tests are currently performed for specimens being analyzed for amphetamines. The rule revision makes the rule consistent with HHS standards and current practices and is therefore expected to have no significant cost impact on licensees.

A change to Section 2.7 (f) (formerly 2.7 [e]) will reduce the screening cutoff level for marijuana from 100 nanograms per milliliter (ng/ml) to 50 ng/ml. Current testing technology is capable of supporting reliable and valid results at this level. In addition, analysis of results in nuclear industry drug testing programs shows that positive test rates (indicating increased detection) increased substantially when the screening level was lowered to 50 ng/ml from 100 ng/ml. These changes will make the NRC's FFD rule consistent with the changes to the HHS Mandatory Guidelines (59 FR 29908) and the cutoff levels used by all other Federal agencies. This change will also ensure that licensees' specimens are tested by a process certified by HHS (any cutoff level different than the HHS-certified process must be accompanied by additional QA measures). This rule change may result in a reduced regulatory burden on HHS-certified laboratories processing specimens for licensees, and may represent a potential cost savings in reduced administrative expense. However, it is uncertain whether these savings will result in reduced laboratory specimen processing costs for licensees, which vary by laboratory and specific contractual agreements. Therefore, these potential savings are not readily quantifiable.

Additional revisions to Section 2.7 (h) (1) eliminate batch reporting requirements, as HHS did in changes to its testing guidelines. Licensees report that laboratory processing time has decreased since the rule was implemented, and that the time to receive test results is usually no more than 24 hours. In some cases results may be held up, but usually this is due to a test result being confirmed, or if a test is suspected of adulteration. In such cases, licensee employees are assigned to other duties as needed, which might entail completing administrative work needed for access, training, and so on.

However, awaiting test results can be a burden on licensees in cases where contractors or new hires are seeking pre-access authorization. Since the HHS Mandatory Guidelines have been revised, the turnaround for test results has been fairly rapid; licensees report that the processing time for specimens sent off-site is usually less than 24 hours. Based on these reports, NRC staff assumes that laboratories are highly responsive in conducting analyses of specimens for licensees, although confirming presumptive positives from on-site testing which are sent to the laboratory for analysis may take longer.

Eliminating batch reporting requirements should represent a potential cost savings to licensees. The potential cost savings would result from reducing the time spent compensating licensee employees, pre-access applicants, and people tested for-cause who are awaiting their test results from the laboratory. In 1995, 79,305 pre-access tests were conducted, or an average of 1,102 tests per FFD program. When test results are held up due to batch reporting, the pre-access applicant may be completing other access requirements (therefore no time is lost awaiting test results for the majority of such cases), or the pre-access applicant may be assigned to other duties outside the protected area. If tests result reports are delayed for many pre-access applicants, then the licensee may incur costs in rescheduling workers and compensating them while awaiting the results, especially during outages when pre-applicant testing is at a peak. A revision to Section 26.24 will eliminate pre-access testing waiting requirements for an estimated one-third (26,170) of the pre-access applicants. Therefore, for purposes of this analysis, it is assumed that the revision would apply to 53,135 applicants, or an average of 738 applicants per FFD program annually.

Licensees are also required to send for-cause test specimens to an HHS-certified laboratory and deny the individual unescorted access pending test results. The person tested for cause and denied unescorted access is usually compensated if the test result is negative. The determination of whether to reassign a person to other duties outside the scope of the FFD rule while awaiting test results depends on the particular circumstances surrounding the for-cause referral. As with pre-access testing, obtaining results in a timely manner is important. In 1995 a total of 763 for-cause tests were conducted, or 10.45 for-cause tests per FFD program. On average, it is assumed that a total of 748 pre-access and for-cause tests are applicable.

For purposes of this analysis, it is assumed that 47 programs send specimens off-site for testing, and that 27 programs conduct on-site testing. Of these 47 licensees, it is assumed that eliminating batch reporting requirements would have no significant cost impact on 75 percent of the licensees (35 programs). It is assumed that 15 percent (7 programs) of the licensees sending specimens off-site would receive their test results one day earlier, and that 10 percent (5 programs) would receive their test results two days earlier.

It is assumed that licensees, on average, currently lose one half (or 50 percent) of the benefit of the employee's or applicant's time for every day that the licensee has to await test results due to batch reporting requirements. Therefore, 7 licensee programs would realize cost savings of 2,992 hours per program (748 person days x 4 hours/day), and 5 licensees would realize cost savings of 5,984 hours per program (1,496 person days x 4 hours/day). Assuming a standard utility labor rate of \$44.78 per hour, 7 licensee programs would each realize an annual cost savings of \$133,981.76 (2,992 hours x \$44.78 per hour), or approximately \$134,000. 5 licensee programs would each realize an annual cost savings of \$267,963.52 (5,984 hours x \$44.78 per hour), or approximately \$268,000.

Licensees testing specimens on-site should realize some savings from eliminating batch reporting requirements as well, although the savings would be much less than programs sending all specimens off-site. It is assumed that 5 percent of the total pre-access tests would be sent off-site for laboratory analysis, or a total of 55 tests (1,102 tests x .05). It is assumed that 20 of the 27 programs conducting on-site testing would realize no savings from the rule change, 15 percent (4 programs) would receive test results one day sooner, and 10 percent (3 programs) would receive test results two days sooner. It is also assumed that licensees, on average, currently lose one half (or 50 percent) of the benefit of the employee's or applicant's time for every day that the licensee has to await test results. For the licensees receiving test results one day sooner, the annual cost savings would be \$9,851.60 (55 tests x 4 hours/test x \$44.78/hour), or approximately \$9,900. For the licensees receiving test results two days sooner, the annual cost savings would be \$19,703.20 (110 tests x 4 hours/test x \$44.78/hour), or approximately \$19,700.

The annual estimated industrywide cost savings from eliminating batch reporting requirements would be \$2,376,700 ([7 programs x \$134,000 per program] + [5 programs x \$268,000 per program] + [4 programs x \$9,900 per program] + [3 programs x \$19,700 per program]), or approximately \$2,377,000.

In response to concerns expressed by some licensees that the rule does not currently require the laboratories to report the results of tests for pH, specific gravity (SG), and creatinine, revision to the regulations will require that the laboratories report these, to the extent these tests

are performed, and any other indications of adulteration or dilution (Section 2.7 [h] [1]). Licensees may specify the data and conditions to be reported in their contract with the laboratory. This revision is not expected to have a cost impact on the licensees.

New wording in Section 2.7 (h) (2) will allow MRO staff to perform routine administrative support functions, including receipt of test results and scheduling interviews for the MRO. Currently the rule requires that only the MRO conduct these administrative activities. This rule change will provide some potential savings in reduced staff time costs. NUREG/CR-5784 reported that in a study of 10 utilities a total of 1,137 GC/MS confirmed positives resulted in 811 positive results declared positive by the MRO. Based on these data, it is assumed that the rate of GC/MS confirmed positives will be higher than the number of positive violations on average by approximately 40 percent (since some of the GC/MS confirmed positives would be declared responsible use or otherwise be determined by the MRO as not being an FFD violation). In 1995, there were an average of 21 violations per FFD program. Therefore, it is assumed that there are an average of 29 confirmed positives per licensee that each MRO must investigate. It is assumed that the MRO would designate administrative responsibility for contacting each person and scheduling interviews to a clerical staff person. Of the 29 test results, it is assumed that 75 percent (or 22 test results) would require an average of 15 minutes of administrative staff time, due to most people being on site and easily reached. It is assumed that 25 percent (or 7 test results) would require an average of half an hour to reach the person who was tested. Therefore, the estimated potential cost savings per FFD program would be the savings in labor costs between an MRO and a clerical staff person conducting this activity. The estimated cost saving per FFD program would be $\$551.16$ ($[(.25 \text{ hours} \times \$94.64 \text{ per hour} - .25 \text{ hours} \times \$33.39 \text{ per hour}) \times 22 \text{ violations} + (.5 \text{ hours} \times \$94.64 \text{ per hour} - .5 \text{ hours} \times \$33.39 \text{ per hour}) \times 7 \text{ violations}]$), or approximately \$600. The total estimated annual industrywide savings would be \$44,400 (74 FFD programs x \$600 per program).

A revision to Section 2.7 (h) (5) will clarify that laboratories shall retain the original custody-and-control forms. The Laboratory is currently required to send a certified copy of the form to the MRO, but is silent on disposition of the original. This disposition will be consistent with the new custody-and-control form mandated for use in testing of Federal employees and workers in the transportation industry. This requirement will ensure that laboratories, which are

currently required to provide expert testimony covering drug test results, will have necessary supporting documentation if so needed. This addition is expected to have no cost impact on licensees.

Minor editorial revisions to Section 2.7 (h) (6) are not expected to result in significant cost impacts.

A revision to Section 2.7 (i) (formerly 2.7 [h]) will add specimens that have been adulterated or diluted, or associated with personnel actions for any other reason, to the types of specimens to be retained for a minimum of one year. Since the current rule requires all confirmed positive specimens to be placed in long-term storage for a minimum of one year, this change would not result in a measurable cost. A revision to Section 2.7 (j) will apply the current retesting standard to specimens that have been adulterated or diluted. This revision may help licensees defend against law suits. However, this change is not expected to have a significant cost impact on licensees.

There are revisions to Section 2.7 (k) (formerly 2.7 [jj]). Several edits have been made to clarify or conform with other changes in the rule. One revision clarifies that the individual must be informed of his or her option to test the split sample. Inspections have indicated that, for various reasons, not all individuals are so informed. A related revision will instruct the licensee to establish a time period within which the individual can request a test of the split specimen. Another revision will clarify the original intent of the rule with respect to the quantitation of test results, similar to the retesting standards in Section 2.7 (j). NRC staff has had to negotiate with laboratory personnel on several occasions regarding providing licensees quantification of test results due to lack of clarity in the current wording of the rule. Another revision to this section will clarify that specimens need not be split in "half." In addition, HHS-certified laboratories are provided a total of three week days (excluding holidays) to forward split specimens to another certified laboratory. A final revision to Section 2.7 (k) will clarify that if a split specimen test result fails to reconfirm the test on a primary specimen, the MRO should continue to have the discretion to determine if a policy violation has occurred. These changes are expected to have no significant cost impact on licensees. This approach is used because the split specimen can deteriorate over time and may produce a negative test result. While this revision involves an

addition to Section 2.7 (k) regarding the MRO's consideration of conflicting results on the primary and split specimen tests, the NRC believes it to be reflective of current industry practice. The addition is intended to clarify the NRC's philosophy that MROs should be making the determination of a violation based on all relevant information. The changes to Section 2.7 (k) are expected to have no significant cost impact on licensees.

A revision to Section 2.7 (m) (formerly 2.7 [l]) will clarify that laboratories must be capable of analyzing blood for alcohol content (BAC); the NRC staff understands that HHS-certified laboratories are currently equipped to conduct blood analysis for BAC. This is to ensure that laboratories are capable of performing this analysis in case of appeal (the individual could choose to send blood, under appeal, to any HHS-certified laboratory) or as otherwise requested by the licensee. This revision is expected to have no cost impact on licensees.

Revisions to Section 2.7 (n) (formerly 2.7 [m]) will require that licensee contracts with HHS-certified laboratories provide the licensee with the ability to obtain copies of any documents or data needed to assure the laboratory's proficiency. In the event that an HHS-certified laboratory loses its certification, the licensee would be permitted to use another HHS-certified laboratory that has been audited by another licensee having a compatible drug panel and cut-off standards until the new laboratory has been audited by the licensee. In that case the licensee would have up to three months to audit the new laboratory (the current rule requires audit before use). This provides for the uninterrupted continuation of testing in the event that a licensee's contracted HHS-certified laboratory loses its certification. This revision should represent a potential cost savings and program efficiencies to licensees since they would be allowed to continue testing specimens during the audit of the new laboratory through another HHS-certified laboratory that has been audited until the licensee's own audit is complete. This revision should result in minimal savings in those few instances of HHS-certified laboratory certification loss. These potential cost savings are not readily quantifiable since they will depend on unique circumstances and opportunities taken by licensees.

Revisions to Section 2.7 (p) (formerly 2.7 [o]) will allow use of alcohol breath analysis equipment that conforms to the September 17, 1993, amendments to the National Highway Traffic Safety Administration's (NHTSA) Model Specifications for evidential breath testing devices

originally published in 1984. While these amendments reflect new lower evaluation thresholds for devices to measure breath alcohol, licensees need not acquire new devices that meet these amended standards. Breath analysis equipment that meets the 1984 NHTSA standards will continue to be acceptable in NRC FFD programs. This flexibility assures that licensees will not be burdened with unnecessary costs. This section is also amended to make explicit the already existing requirement that calibration units used to calibrate alcohol breath analysis equipment conform to current NHTSA standards. These changes are expected to provide indeterminate savings.

Another revision to Section 2.7 (p) will require HHS-certified laboratories to retain a copy of their latest procedure manual until two years after they are no longer under contract with a licensee. Section 2.7 (p) clarifies the current requirement that calibration standards must be current and valid for their purpose. This should help licensees defend against challenges to accuracy of on-site testing (including BAC testing) and would provide indeterminate savings. Also, licensees conducting on-site testing must retain a copy of their procedure manuals until they are no longer conducting on-site testing. These changes should have no cost impact.

2.8 Quality Assurance and Quality Control

Editorial revisions to Sections 2.8 (a) (b) and (c) are expected to have no cost impact on licensees. A revision to Section 2.8 (b) requires that results of blind QC testing must be evaluated and appropriate corrective actions taken. Otherwise similar errors on real specimens could result in successful law suits. This revision is not expected to have a significant cost or savings impact on licensees.

A revision to Section 2.8 (e) (1) will clarify the criteria that licensees must follow when purchasing blind quality control specimens. Currently requirements only ensure that blind quality control materials be purchased from labs certified by HHS or a HHS-recognized certification program. Due to the fact that not all suppliers of blind quality control materials adhere to uniform standards for preparation and certification of content, unacceptable blind quality control specimens have been used. These unacceptable blind quality control test results, e.g., false

negatives or false positives, lead to increased costs and lowered efficiency because of additional tests and follow-up actions necessary to validate the results of previously tested actual specimens. In order to eliminate these problems, the revision explicitly states the criteria, as HHS did in the revisions to its Mandatory Guidelines, in order to clarify for licensees the standards for blind quality control materials and make the rule consistent with existing practice. Staff believes that the rule change could provide potential savings to licensees in reducing the total number of investigations that have been required for unsatisfactory blind performance specimens. Data accumulated since 1990 indicate that approximately 50 percent of the problems are caused by manufacturers' formulation or packaging of blind quality control specimens. It is assumed that 50 percent of licensees use acceptable specimens. It is further assumed that the rule change would eliminate ten investigations of unsatisfactory blind performance specimens per year for the remaining 37 licensee programs. Each investigation is assumed to require three days of staff time, not including the time spent by the laboratory investigating such occurrences. (Laboratories may choose to charge directly for such an investigation, or assume the cost of the investigation; laboratory practice in this regard depends on specific contracting arrangements with the licensee and therefore is not easily quantifiable.) It is assumed that the investigation would require one day of the licensee MRO's time, one day of the FFD program manager's time, and one day of a clerical staff person's time. Therefore, the estimated cost savings for reducing one investigation would be \$1,589.92 (8 hours x [\$94.64 plus \$70.71 plus \$33.39], or approximately, \$1,600. The total estimated annual industrywide savings would be \$16,000 (10 FFD programs x \$1,600 per program).

Revisions to Section 2.8 (e) (2) reduce the number of blind performance test specimens that licensees are required to submit for analysis as part of their FFD quality assurance and quality control program. Blind performance test specimens are needed to assure that the results of an employee's specimen are valid. However, after consulting with SAMHSA, noting that the Department of Transportation has reduced its continuing rate to 3 percent, and recognizing the total volume of tests conducted, the NRC believes the percentage of blind performance tests can be reduced. During the initial 90-day period of any contract with a HHS-certified laboratory, the minimum number of blind performance test specimens to be submitted for analysis would be lowered from 50 percent of the total samples submitted to 20 percent, or 30 blind performance test specimens, whichever is greater. The maximum number of blind performance test

specimens to be submitted during the initial 90-day period would be lowered from 500 specimens to 100 specimens. After the initial 90-day period, the minimum number of blind performance test specimens required for submittal on a quarterly basis would be lowered from 10 percent of all samples submitted to 3 percent, or 10 blind performance specimens, whichever is greater. The NRC believes that 3 percent of the small volume of tests under some licensees' programs, particularly where on-site testing is significantly reducing the number of specimens sent to the HHS-certified laboratory, may not provide adequate quality assurance that test results are valid. HHS staff shared this concern. The NRC believes that requiring a minimum number of blind specimens rather than a minimum percentage would ensure that a sufficient number are submitted to assure the quality of the testing process. This is particularly applicable for licensees performing on-site screening of specimens and therefore having very few unconfirmed positive test results to submit to laboratories. The maximum number of blind performance test specimens to be submitted after the initial 90-day period is lowered from 250 specimens to 25 specimens per quarter. The maximum number of blind performance test specimens required to be submitted both in the initial 90-day period and after better reflects the number of blind performance test specimens needed to assure laboratory quality.

These rule changes represent potential cost savings to licensees. Assuming that each FFD program currently submits an average of 1,200 samples annually for analysis, and assuming that an amount equal to 10 percent of blind performance specimens are submitted, it is estimated that each FFD program not conducting on-site testing currently submits an average of 120 blind performance test specimens for analysis annually. The rule revision would reduce this number to an average of 36 specimens, resulting in an estimated potential reduction of 84 specimens submitted for testing annually. Assuming the preparation of each test specimen, testing, and reporting of results is \$65 per specimen, the estimated potential cost savings for the 47 licensee FFD programs not conducting on-site testing would be \$5,460 (84 blind performance specimens x \$65 per specimen), or approximately \$5,500. For the estimated 27 licensee FFD programs conducting on-site testing, it is assumed they send an average of ten percent of negative screens (1,200 specimens minus one percent [positive screens] x 10 percent) plus positive screens (one percent, or 12 total), resulting in a total of 13 blind performance specimens for testing each year. The revision would reduce the number of blind performance specimens to 4 specimens, a savings of \$585 ((13 - 4) specimens x \$65 per specimen), or approximately \$600.

The total estimated potential industrywide cost savings would be \$286,700 ([47 FFD programs x \$5,500 per program] plus [27 FFD programs x \$600 per program]), or approximately \$287,000.

Revisions to Section 2.8 (e) (3) will reduce the number of blind performance test specimens that would have to be blank from 80 percent to 50 percent of the total number of blind performance specimens and require that 10 percent of the positive blinds be adulterated or diluted and spiked to between 60 and 80 percent of the licensee's cut off-level. These revisions are expected to have no significant cost impact on licensees and provide improved quality of information needed to defend against legal challenges to the accuracy of laboratory testing results.

Revisions to Section 2.8 (f) (1), (2), and (3) (formerly Section 2.8 [e] [4], [e] [5], and [e] [6]) clarify guidelines concerning the investigation of testing errors and related matters. One revision requires licensees to investigate any testing errors or unsatisfactory performance identified throughout the testing process or during the appeals process. The NRC intended, in the original rule, that testing or process errors discovered in any part of the program, including the appeals process, be considered an unsatisfactory performance of a test. Thorough investigation and reporting of such test results will continue to assist the NRC and its licensees, HHS in its role of administering the laboratory certification program, and the HHS-certified laboratories in preventing future occurrences and in raising the quality of the testing process. Through improved QC and remedial actions, these actions also should help licensees defend against lawsuits which challenge the accuracy of laboratory test results. Therefore, the change should result in indeterminate savings. Companion changes to Section 2.8 (e) (1) are expected to produce a cost savings by reducing the number of investigations industrywide by restating the criteria for blind quality control specimens. Another revision to Section 2.8 (f) (1) establishes an explicit retention period for records of investigative findings of three years. Since it is assumed that licensees are now retaining such records indefinitely, this revision could be expected to produce some minimal, uncalculated savings.

2.9 Reporting and Review of Results

Revisions to Section 2.9 (b), (e), and (f) will clarify the original intent of the rule with regard to the MRO's responsibilities for reporting and reviewing laboratory confirmed positive test results and are expected to have no significant cost impact on licensees. A revision to Section 2.9 (b) adopts a recent change to the HHS Mandatory Guidelines by prohibiting the MRO from having any conflict of interest in the testing process.

A revision to Section 2.9 (c) will clarify that the MRO must immediately notify management and the EAP of positive test results that have been verified as a violation of FFD policy. This revision has already been addressed in Section 26.24 (f), and is expected to have no significant cost impact on licensees. Also, an addition to Section 2.9 (c) stipulates that the MRO may, under certain circumstances, verify a laboratory confirmed positive test result as a FFD policy violation, or make a determination of violation of FFD policy for other reasons, without having communicated with the employee. Section 2.9(c) is also revised to expand its coverage from only positive test results to all FFD policy violations. These revisions are expected to facilitate the resolution of FFD matters and to have an indeterminate cost savings for licensees.

Revisions to Section 2.9 (d) clarify that the standards applied to determining whether clinical evidence exists that would support verification of a laboratory confirmed positive test result as a violation of FFD policy include other evidence in addition to needle marks. Some MROs had interpreted this as restrictive, therefore most opiate positives reported by the laboratory were declared negative by the MRO. The revisions also eliminate the requirement that MROs investigate clinical evidence of unauthorized use of over-the-counter drugs. This requirement has created difficulties for Medical Review Officers because there is little guidance that can be developed regarding what constitutes clinical signs of abuse for these substances. However, the revisions do allow the MRO to consider admission of non-prescribed opiate use. These revisions are expected to have minor indeterminate savings.

Revisions to Section 2.9 (e) will authorize licensees to establish the period within which a tested employee may request a reanalysis of a specimen after notification of a positive test result. This provision protects the licensees from requests for reanalysis that are not timely. Instances of individuals not being informed about reanalysis and of individuals requesting reanalysis after significant time has elapsed have occurred. This is also compatible with new HHS Mandatory

Guidelines provisions with respect to the donor requesting a test of the split sample. However, under the HHS approach the split specimen belongs to the donor, the primary specimen belongs to the employer. Section 2.9 (f) will clarify MRO responsibilities concerning the determination of results consistent with responsible substance use and, if there is a potential risk to public health and safety, to initiate a "medical determination of fitness." These revisions are expected to have no significant cost impact on licensees.

A new Section 2.9 (g) clarifies requirements for "medical determination of fitness." There would be a requirement that a medical determination of fitness be conducted in the following cases: (1) where there is a reason to believe that on-duty impairment may exist (whether or not there is an FFD policy violation), (2) prior to making return-to-duty recommendations, (3) prior to granting unescorted access to the protected area when a record of a prior FFD violation exists, and (4) if a history of substance abuse is otherwise identified. The licensed physician or Medical Review Officer is to report to licensee management both determinations of FFD violations and determinations of any condition under which an individual may not be able to safely and competently perform his or her duties. These requirements are intended to increase assurance that a medical evaluation is performed for circumstances where fitness may be questionable. These revisions clarify the original intent of the rule and are expected to have no significant cost impact on licensees.

A revision to Section 2.9 (h) (formerly Section 2.9 [g]) will allow licensees to dispose of records of findings of negative test results based on scientific insufficiency after three years. Because this section currently requires licensees to retain such records of an infrequent event for an indefinite period, this revision should produce minimal, uncalculated savings.

3.1 Protection of Employee Records

No changes to this section.

3.2 Individual Access to Test and Laboratory Certification Procedures

The cost implications of revisions to this section have been previously described in the discussion of a new Section 26.29 (c).

4.1 Use of HHS-Certified Laboratories

Revisions to this section are expected to have no cost impact on licensees.

3.3.3 Summary of Benefit and Cost Estimates

Table 6 provides a summary of total estimated savings and costs.⁴¹ Table 7 provides a summary of identified potential savings and costs for the rulemaking by rule section. As in the rest of this document, the savings and cost amounts in these tables are in 1995 dollars. The estimated one-time industrywide costs would be \$165,000 (\$17,000 industrywide for increasing the scope of the rule to include FFD program personnel and \$148,000 for initial policy and procedure revisions in compliance with the revised rule). It is assumed initial industrywide costs will be incurred when the revised rule is implemented.

All recurring savings and costs will be incurred on an annual basis following the implementation of the rule for an estimated average industrywide remaining plant life of twenty years.⁴² The estimated recurring industrywide annual operating savings resulting from the rule changes would be \$27,723,000. Assuming a seven percent discount rate, the discounted savings resulting from the rule changes would be \$293,864,000 over twenty years. The estimated recurring industrywide annual operating costs to implement the rule changes would be \$856,000. The discounted costs of the rule changes that would be incurred over the twenty years has a present value of \$9,074,000.

⁴¹Present value (PV) was calculated using the discrete discounting method described in NUREG/BR-0184, *Regulatory Analysis Technical Evaluation Handbook*, January 1997.

⁴²The twenty year average remaining lifetime of all plants is based upon information provided in NUREG/BR-0184 and takes into account the potential for some plants to acquire license extensions.

Therefore, the rule changes would save licensees an estimated \$26,702,000 [\$27,723,000 - (\$165,000 + \$856,000)] industrywide in the first year following the rule changes, and \$26,867,000 (\$27,723,000 - \$856,000) annually thereafter. These net savings, discounted at seven percent over the twenty year period, would produce a total net industrywide savings of approximately \$284,625,000 over that period.⁴³ Although other potential cost savings were identified, these savings were not readily quantifiable.

Table 6. Total Estimated Savings and Costs

	Industry Savings	Industry Costs
Initial Savings/Costs	--	\$165,000
Annual Recurring Savings/Costs	\$27,723,000	\$856,000
Present Value (Total)	\$293,864,000	\$9,074,000

For purposes of sensitivity analysis to recognize the uncertainty of economic conditions over the estimated industrywide average remaining plant life of twenty years, these savings and cost figures can be considered using an alternative real annual discount rate of three percent. Using this discount rate, the present value of the estimated recurring industrywide annual operating savings of \$27,723,000 over the twenty year period would be \$413,073,000. The present value of the estimated industrywide annual costs of \$856,000 would be \$12,754,000. Taking into account the estimated one-time industrywide costs of \$165,000 that would be incurred in the first year of rule revision implementation, the present value of the industry's net savings over the twenty year period would be approximately \$400,153,000, assuming a three percent annual discount rate.

⁴³This present value of the net savings was calculated by deducting the \$165,000 of one-time costs that will be incurred in the first year from \$284,790,000, the present value of the twenty year stream of annual net savings.

Table 7. Estimated Annual Costs and Savings of Rulemaking by Rule Section

Rule Section	Description	Cost	Savings	FFD Programs/ Reactor Units Affected ¹	Industry Costs	Industry Savings
26.2 Scope	<p>Include FFD program personnel within scope of rule</p> <p>Eliminate duplicate testing</p>	<p>\$1,100*</p> <p>\$400*</p> <p>\$280</p> <p>\$140</p>	\$2,800	<p>2 FFD Programs</p> <p>37 FFD Programs</p> <p>2 FFD Programs</p> <p>37 FFD Programs</p> <p>74 FFD Programs</p>	<p>\$17,000*</p> <p>\$6,000</p>	\$207,000
26.20 Overall Policy and Procedure Revisions	<p>Permit licensees to grant unescorted access to personnel covered by another program</p> <p>Policy and procedure revision costs for revised rule</p>	\$2,000*	\$100	<p>112 Reactor units/ nuclear fuel facilities</p> <p>74 FFD Programs</p>	\$148,000*	\$11,000

Table 7 (continued)

Rule Section	Description	Cost	Savings	FFD Programs/ Reactor Units Affected ¹	Industry Costs	Industry Savings
26.21 Policy Communication and Awareness Training	Accept training of other licensees		\$13,100	112 Reactor units/ nuclear fuel facilities		\$1,467,000
	Extend refresher training interval from once every 12 months to once every 24 months		\$61,000	112 Reactor units/ nuclear fuel facilities		\$6,832,000
26.22 Supervisory Training	Accept training of other licensees		\$2,300	112 Reactor units/ nuclear fuel facilities		\$258,000
26.24 (a) (1)	Revisions to pre- access testing requirements		\$7,000	112 Reactor units/ nuclear fuel facilities		\$784,000
			\$43,000	112 Reactor units/ nuclear fuel facilities		\$4,816,000
			\$7,000	112 Reactor units/ nuclear fuel facilities		\$784,000
				112 Reactor units/ nuclear fuel facilities		

Table 7 (continued)

Rule Section	Description	Cost	Savings	FFD Programs/ Reactor Units Affected ¹	Industry Costs	Industry Savings
26.24 (a) (3)	Revisions to for- cause testing requirements		\$2,000	74 FFD Programs		\$148,000
26.24 (a) (5)	Return-to-duty testing	\$500	\$14,600	45 Reactor units/ nuclear fuel facilities	\$56,000	\$657,000
			\$4,400	112 Reactor units/ nuclear fuel facilities		\$493,000
			\$11,800	112 Reactor units/ nuclear fuel facilities		\$1,322,000
				112 Reactor units/ nuclear fuel facilities		
26.24 (e)	Minimize testing notification time		\$1,600	74 FFD Programs		\$118,000

Table 7 (continued)

Rule Section	Description	Cost	Savings	FFD Programs/ Reactor Units Affected ¹	Industry Costs	Industry Savings
26.27 (a) (6)	Grant temporary unescorted access after completion of 1st year suitable inquiry		\$36,000	74 FFD Programs		\$2,664,000
26.28 Appeals	Appeals process extended to all applicants denied access	\$500		112 Reactor units/ nuclear fuel facilities	\$56,000	
26.29 Protection of Information	Information provided upon request	\$200		112 Reactor units/ nuclear fuel facilities	\$22,000	
26.71 Recordkeeping Requirements	Reduce the submission of program performance reports		\$2,000	74 FFD Programs		\$148,000
26.73 Reporting Requirements	Report significant FFD events	\$100		74 FFD Programs	\$7,000	

Table 7 (continued)

Rule Section	Description	Cost	Savings	FFD Programs/ Reactor Units Affected ¹	Industry Costs	Industry Savings
26.80 Audits	Reduce audit frequency		\$7,000	74 FFD Programs		\$518,000
	Reduce HHS audit redundancies		\$600	50 FFD Programs		\$30,000
			\$400	24 FFD Programs		\$10,000
Appendix A						
2.2 General Administration of Testing	Reduce record retention requirements		\$11,500	74 FFD Programs		\$851,000
2.3 Preventing Subversion of Testing	Reduce background evaluation frequency for FFD personnel		\$100	74 FFD Programs		\$7,000
2.4 Specimen Collection						
2.4 (g) (9)	Eliminate record book requirement		\$2,100	74 FFD Programs		\$155,000
2.4 (g) (11)	Provide flexibility in specimen volume		\$1,200	74 FFD Programs		\$88,000

Table 7 (continued)

Rule Section	Description	Cost	Savings	FFD Programs/ Reactor Units Affected ¹	Industry Costs	Industry Savings
	Stipulate that partial specimens are not to be contained in one container	\$8,000		74 FFD Programs	\$596,000	
2.4 (g) (18)	Eliminate second breath test		\$10,400	112 Reactor units/ nuclear fuel facilities		\$1,165,000
2.4 (i)	Preventing specimen degradation	\$1,200 \$10,700		5 FFD Programs 10 FFD Programs	\$6,000 \$107,000	
2.7 Laboratory & Testing Analysis Procedures						
2.7 (e)	Determining specimen validity	\$2,500	\$19,800 \$19,800	27 FFD Programs 47 FFD Programs	\$67,500	\$534,600 \$930,000
2.7 (h) (1)	Eliminate batch reporting requirements		\$134,000 \$268,000 \$9,900 \$19,700	7 FFD Programs 5 FFD Programs 4 FFD Programs 3 FFD Programs		\$2,377,000

Table 7 (continued)

Rule Section	Description	Cost	Savings	FFD Programs/ Reactor Units Affected ¹	Industry Costs	Industry Savings
2.7 (h) (2)	Flexibility in performing administrative support		\$600	74 FFD Programs		\$44,400
2.8 Quality Assurance and Quality Control						
2.8 (e) (1)	Clarify blind performance specimen criteria		\$1,600	10 FFD Programs		\$16,000
2.8 (e) (2)	Reduce blind performance testing rate		\$600 \$5,500	27 FFD Programs 47 FFD Programs		\$287,000
TOTALS	Estimated annual industrywide costs and savings				\$165,000* \$856,000	\$27,723,000

*Figures denoted with an asterisk are one-time initial costs only.

¹Depending on where impacts are most likely to occur, i.e., at FFD program level or reactor unit level.

Note: Discrete costs and savings are rounded to nearest hundred dollar; industry costs and savings are rounded to nearest thousand dollar.

3.4 IMPACT ON OTHER REQUIREMENTS

The principal impact of the revisions will be on affected licensees and licensee employees. The cost impact on licensees is discussed in Section 3.3. Impacts on other government agencies are expected to be minimal. The impacts on NRC programs and requirements are also expected to be relatively small. The NRC has used existing personnel for regulatory activities concerning FFD programs since 1982. The NRC does not anticipate the need to add any additional staff or administrative personnel as a result of this rulemaking. The administration of the revised rule will be absorbed by current personnel and staff.

4.0 DECISION RATIONALE

Of the alternative approaches considered, the NRC staff believes that comprehensive rulemaking is appropriate (see Section 2.2.1). Public comments were requested and have been received and responded to as to whether the recommended changes can be better addressed by other means (see Section 2.2.2).

This rulemaking is being conducted to ensure that Part 26 continues to effectively address two related concerns. The safety concern addressed by Part 26 is that evidence has shown that use of alcohol or drugs can impair a worker's motor skills and judgment sufficiently that accidents arising from neglect or human error are more likely to occur. The trustworthiness concern addressed by Part 26 is that licensee employees who knowingly use illegal drugs or abuse legal drugs or alcohol willingly violate the standards set by the licensee as well as society's laws and norms and therefore cannot be trusted to carry out their duties in a safe and secure manner. Although overall results indicate that licensee fitness-for-duty programs are working well, the changes are intended to ensure that the general performance objectives expressed in Section 26.10 are achieved. These general performance objectives are:

- ! Provide reasonable assurance that affected workers will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;
- ! Provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of the rulemaking; and
- ! Further the goal of achieving a drug-free workplace and a workplace free of the effects of such substances.

While the staff concludes that the rule is fundamentally sound and provides a means for both detection and deterrence and that no fundamental changes to Part 26 are needed, lessons learned during the past eight years of rule implementation indicate that there are a number of issues that should be addressed. These issues include subversion, inefficiencies in the current rule that, if revised, would substantially lessen the regulatory burden on licensees, regulatory friction in overlapping mandates between other federal drug testing programs and the NRC requirements, a need to clarify the original intent of the Commission by correcting ambiguous wording in the current rule, and a need to address technical developments in light of improved drug and alcohol testing practices.

5.0 IMPLEMENTATION SCHEDULE

5.1 SCHEDULE FOR IMPLEMENTING THE REQUIREMENT

These requirements are to be implemented 90 days from the date that the final rule is published.

5.2 RELATIONSHIP TO OTHER EXISTING REQUIREMENTS

The amendments to Part 26 requirements would also apply to licensees authorized to possess, use, or transport Category I Material. Appendix A to Part 26 is the NRC's adaptation of the "Mandatory Guidelines for Federal Workplace Drug Testing Programs," issued by the Department of Health and Human Service (53 FR 11970, April 11, 1988 and revised 59 FR 29908, June 9, 1994).

ATTACHMENT F

**ANALYSIS OF THE APPLICATION
OF THE BACKFIT RULE TO THE REVISIONS
TO THE FITNESS-FOR-DUTY RULE**

**ANALYSIS OF THE APPLICATION OF THE BACKFIT RULE
TO THE REVISIONS TO THE FITNESS-FOR-DUTY RULE
(10 CFR PART 26)**

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**ANALYSIS OF THE APPLICATION OF THE BACKFIT RULE
TO THE REVISIONS TO THE FITNESS-FOR-DUTY RULE
(10 CFR PART 26)**

This paper presents the staff's analysis of the application of the NRC's Backfit Rule (10 CFR 50.109) to each individual revision to the Fitness-for-Duty rule (10 CFR Part 26). As explained in the Federal Register notice associated with this rulemaking, the Commission also performed and relied upon a backfit analysis considering all the changes in the aggregate. Thus, this paper provides only part of the backfit analysis upon which this rulemaking is based.

In publishing the proposed revisions to Part 26 on May 9, 1996 (61 FR 21105), the NRC listed the revisions in three groups to facilitate the public's consideration. Group I included revisions that would conform Part 26 requirements to other national standards, including the Department of Health and Human Services' *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (referred to as HHS Mandatory Guidelines throughout this document). Group II included revisions that would reduce licensee burden and Group III included revisions that would be worthwhile for other reasons. Minor edits that would make no substantive change were not included in that list and, therefore, are not included in this analysis. This paper describes each of the proposed Part 26 revisions in the order that they were listed in these three groups. For reasons of clarity, the staff has split a few revisions that were included on the original list into two separate revisions. In these cases, the revision that did not appear as a separate revision on the list is designated as "NEW" in this document. It should also be noted that the staff is now recommending, based on public comments or new information, some modifications to the rule revisions that were published in the NRC's May 9, 1996, Federal Register notice. For the revisions that have been modified, the description of the revision indicates the nature and reason for the modification and the application of the Backfit Rule to the modification. An index at the end of this analysis gives the page numbers on which revisions to specific rule sections appear.

The grouping of the proposed revisions in this document is the same as the grouping in the statement of consideration (SOC) for the proposed FFD Rule (61 FR 21105, 21129), and has no relationship to the backfitting classifications for each of the revisions. For example, some revisions that result in reduction in burden are listed under Group I (Adoption of National Standards), and not under Group II, (Reductions in Burden).

Background

The Backfit Rule, 10 CFR 50.109, sets forth certain requirements with respect to backfitting. Thus, the first task in evaluating whether a proposed action is subject to the Backfit

Rule is whether the agency action constitutes "backfitting." Section 50.109(a)(1) defines backfitting as:

the modification of or addition to...the procedures or organization required to...operate a facility...which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position....

Based upon this definition, the Staff has taken the position that a backfit does not exist (and a backfit analysis is not required) where the proposed regulatory provision is optional or voluntary, or where there is a permissive relaxation of requirements (viz., the licensee is not required to comply with the relaxed requirements, but is free to continue to comply with the pre-existing, more stringent requirements). See NRC's *Backfitting Guidelines* (NUREG-1409, July 1990).

Assuming that a proposed agency action is a backfit as defined in Section 50.109(a)(1), Section 50.109(a)(3) requires that a backfit analysis of the proposed agency action be prepared which demonstrates that:

there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

However, Section 50.109(a)(4) sets forth three exceptions to the paragraph(a)(3) requirement for a backfit analysis. One of these, the "compliance exception," exempts modifications that are "necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee...." 10 CFR 50.109(a)(4)(i). The compliance exception is appropriate only where there is an existing regulatory requirement or clearly stated Commission intent that is not currently being met. The other two exceptions are where the backfit is necessary for assuring adequate protection, see 10 CFR 50.109(a)(4)(ii), or where the NRC is defining, or redefining what is necessary for adequate protection, see 10 CFR 50.109(a)(4)(iii).

A Staff Requirements Memorandum (SRM) dated June 30, 1993 (SECY-93-086), contains additional guidance regarding Backfit Rule implementation. In that SRM the Commission stated that it expects the Backfit Rule's "substantial increase" criterion to be flexibly administered. Accordingly, qualitative as well as quantitative arguments can be made to

demonstrate that a given proposed rule would substantially increase safety. The Commission also noted that this approach is flexible enough to allow for arguments that proposed rules that would make NRC requirements consistent with national and international standards, or would incorporate widespread industry practices, can either directly or indirectly create a substantial increase in safety.

The Commission also recognized that there may be worthwhile changes which, in the staff's opinion, do not meet the "substantial increase" standard but should be promulgated mainly for non-safety reasons. The Commission stated that it is willing to consider, on an case-by-case basis, whether such worthwhile changes should be promulgated as exceptions to the Backfit Rule as long as the proposal not to apply the Backfit Rule has been the subject of public notice and comment.

Public Comments on Application of Backfit Rule

The NRC published its proposed revisions to the FFD rule on May 9, 1996 (61 FR 21105). Of the 35 entities and one person that submitted written comments on the proposed revisions, 12 submitted specific comments and recommendations pertaining to application of the Backfit Rule. This section briefly discusses the backfit-related comments and recommendations of three primary commenters: the Nuclear Utility Backfitting and Reform Group (NUBARG), the American Association of Medical Review Officers (AAMRO), and NEI.

In NUBARG's view, the Backfit Rule applies only to proposed rules that would create new obligations for licensees. Therefore, rule changes that would reduce existing licensee requirements and burden, and that do not obligate licensees to engage in any new mandated actions, would not be backfits. New or modified requirements, however, should be subject to backfit requirements. NUBARG cited various kinds of new or modified requirements that it believes should be considered backfits, including those that would enhance efficiency and decrease licensee or NRC costs. Backfit requirements for such new or modified requirements can be addressed in various ways. For example, new or modified requirements can be promulgated as an alternative to the existing regulation. In such cases, NUBARG believes the Backfit Rule would be inapplicable because the new requirements would not be imposed on licensees. Instead, licensees would have the discretion of following either the existing or the new requirements.

If compliance with new or modified requirements is to be non-discretionary, NUBARG stated that the Backfit Rule obligates the NRC to conduct an appropriate backfit analysis. NUBARG recommended, however, that the Commission take a practical approach to backfit requirements. In those cases where proposed new requirements would improve efficiency and

reduce licensee costs, the NRC should adopt them even though they may not satisfy the “substantial increase in safety” standard. In NUBARG’s opinion, the purpose of the Backfit Rule would not be served by applying an overly broad interpretation of the rule that precludes new or modified requirements which actually benefit licensees. To do so would be to elevate form over substance.

NUBARG also recommended that, in cases when a rulemaking involves some individual rule revisions that would reduce burden and others that would increase requirements, the Commission should address each provision separately or in groups of similar provisions. A backfit review is not necessary for individual or groups of provisions that represent reductions in requirements. Provisions that would impose new requirements, on the other hand, must be justified by a backfit review. NUBARG recommended that the NRC not promulgate the proposed FFD rule revisions as exceptions to the Backfit Rule.

In contrast to NUBARG, the American Association of Medical Review Officers would have the Commission proceed with this rulemaking without addressing Backfit Rule requirements. In AAMRO’s view, the proposed rule revisions as a whole do not constitute a backfit because their cumulative effect would be to significantly improve the effectiveness of the FFD program. AAMRO noted that drug abuse is a chronic and dynamic problem. Rather than remaining static, FFD programs must instead keep pace with changes in drug abuse patterns, methods of drug detection avoidance, and new technologies. Technical changes to FFD programs are essential to maintain effectiveness. AAMRO asserted that the backfit analysis requirement is an obstacle to maintaining this effectiveness. In AAMRO’s view, application of the Backfit Rule to proposed FFD program changes essentially requires that the program must come close to becoming ineffectual before regulatory changes can be made. AAMRO recommended that the NRC not apply Backfit Rule requirements to the proposed Part 26 revisions because safety programs should not have to run to the brink of failure before corrective action can be taken.

NEI, whose comments were endorsed by 12 of the 17 power reactor licensees that commented on the proposed rulemaking, presented a third assessment of how the NRC should approach its Backfit Rule obligations. NEI stated that it supports most of the proposed FFD rule revisions and recommends that many of those revisions should be enacted promptly. In NEI’s view, early implementation of these revisions will add clarity to the existing rule and reduce licensee burden without affecting public health and safety. Like NUBARG, NEI recommended that the NRC not promulgate the proposed rule revisions as exceptions to the Backfit Rule. Of the 5 power reactor licensees that did not fully endorse NEI’s comments, one specifically requested that the NRC go forward without further backfit analysis, as long as licensee comments are sufficiently considered.

While expressing support for many of the specific revisions, NEI also called out several proposed revisions that it believed require backfit justification. The organization presented these particular revisions in two general categories. In NEI's view, some of these proposed revisions would clearly be burdensome. NEI asserted that the proposed revisions in this category must be justified as backfits before they can be adopted by the Commission. The second category included proposed revisions that NEI believes can be changed to avoid creating new burdens and it provided recommendations about how these proposed revisions should be changed. If the NRC declines to adopt its suggested changes, however, NEI requested that proposed rule revisions in this second category should also be justified as backfits. NEI recommended that the Commission remove those proposed revisions that require backfit justification from the current rulemaking process and proceed to quickly adopt the majority of rule revisions that have no backfit impact.

Several of NEI's comments did not actually raise a backfit issue. Instead, these comments were recommendations for changes to the underlying rule requirement or proposed rule revision. NEI's recommendations and response are included in the analysis of the related revision.

Staff Recommendations on Application of Backfit Rule

The NRC staff has carefully reviewed each revision and has concluded that they are needed and should be promulgated. The staff recommends that the complete package of proposed revisions be promulgated without further backfit consideration. In the staff's view, this current rulemaking as a whole will both provide an incremental improvement in the protection of the public health and safety and reduce licensee burden. To provide some perspective on the current level of effectiveness achieved by the current FFD rule, there have been 13,237 positive test results from January 1990 through the end of December 1997. Pre-access testing identified 8,920 applicants as positive; 4,317 workers with unescorted access to the protected areas were positive for illegal drugs or alcohol. During the same period, 93 licensed operators, 151 licensee supervisors, and 119 contractor supervisors violated a licensee's FFD policy.

The Regulatory Analysis prepared for this rulemaking indicates that the complete package of revisions would save the industry approximately \$27.7 million per year and \$300 million over the next two decades. The large majority of the proposed revisions are clearly not backfits. They would create relatively minor program adjustments, many of which would increase program effectiveness and efficiency and decrease burden on licensees. The Staff also notes that the industry costs associated with the one-time modifications to licensees' policies and procedures which would be necessitated by *all* changes in this rulemaking package (including all

administrative matters and clarifications, as well as all of the proposed worthwhile changes) are estimated to be \$148,000.

Based on the guidance provided by the *Backfitting Guidelines* and the June 1993 SRM, the staff has determined that each revision fits into at least one of the following classifications:

- 1) Clarifications. Several revisions would clarify current requirements to assure consistent understanding and implementation of the Commission's original intent for these requirements. Inquiries from licensees, attorneys, and NRC inspectors during the past eight years about the specific meaning of certain rule sections indicate that the current wording of those sections does not clearly convey the Commission's original intent. The staff has responded to these inquiries by providing verbal guidance as to the Commission's intent and the staff is confident that most licensees are now properly implementing these requirements. However, since the inquiries continue, clarifications are deemed necessary. While not changing the requirements stated in these sections, the revisions would remove the ambiguities that produced the licensees' uncertainty. The revisions would minimize the possibility for any future confusion, uncertainty, and misperception. According to an Office of General Council (OGC) memo interpreting the Backfit Rule, the rule does not apply to rule revisions that leave current requirements unchanged (memo from M. G. Malsch to Commissioner Asselstine, January 23, 1986). Because the revisions clarify, but do not change current requirements, the staff concludes that the revisions are not backfits as defined in 10 CFR 50.109(a)(1).
- 2) Administrative matters. Revisions such as correction of typographic errors, correction of inconsistencies, relocating requirements from one section to another, and combining existing requirements into a single section, are administrative matters which, as the *Backfitting Guidelines* document notes, are not subject to Backfit Rule requirements.
- 3) Permissive Relaxations. These revisions are not subject to the Backfit Rule's requirements because they are permissive relaxations of current requirements (i.e., licensees are free to either comply with current requirements or adopt the relaxed requirements as an alternative). Several revisions will provide licensees with the opportunity to reduce costs but do not require licensees to adopt a change. As the *Backfitting Guidelines* document notes, the Backfit Rule does not apply to permissive relaxations of regulatory burden.

- 4) Information collection and reporting requirements. Information collection and reporting requirements are not considered to be backfits as set forth in the Committee to Review Generic Requirements (CRGR) charter. It should be noted that all information collection and records retention requirements contained in this rulemaking have been approved by the Office of Management and Budget (OMB) approval number 3150-0148, and that the OMB submittal with respect to this rule contains an analysis of the costs and burdens associated with the information collection and reporting requirements contained in the rule.

- 5) Compliance exceptions. These revisions fit under the Backfit Rule's compliance exception. This exception encompasses rule revisions that are necessary to bring licensees into compliance with existing Commission requirements or the Commission's clearly stated intent in promulgating the requirement. The staff is aware that some licensee FFD programs do not currently fully comply with certain Part 26 requirements, sometimes because of differences in interpretation of ambiguous language in the regulations. Therefore, the purpose of some of the proposed revisions is to restate or otherwise clarify the requirements so that these licensees' FFD programs may be brought into compliance with those particular requirements. In addition, some of the proposed revisions modify current requirements where there is evidence that the current version of the standards is not achieving the purpose that the Commission had when it originally promulgated the rule.

- 6) Worthwhile Changes to be Adopted as Backfit Rule Exceptions. The staff recommends that the Commission consider worthwhile revisions for promulgation as exceptions to the Backfit Rule as authorized by the June 30, 1993 SRM discussed above. These worthwhile revisions neither fit into one of the three exceptions in the Backfit Rule (10 CFR 50.109(a)(4)(i) through (iii)), nor can the staff conclude that the change represents a substantial increase in safety whose costs are justified in view of the increased protection. Accordingly, the staff recommends that these worthwhile changes be adopted as exceptions to the Backfit Rule.

NOTE: Many of the worthwhile changes are recommended to clarify, or ensure compliance with, an original Commission intent that was not explicitly documented, and therefore cannot be justified as "compliance exceptions" under Section 50.109(a)(4)(i).

For each of the changes listed the following items are provided:

- ! *Revision:* A brief description of the rule change.
- ! *Purpose:* A discussion of why the rule change is necessary.
- ! *Licensee Cost Reduction/Increase:* An estimate of the cost impact on licensees.
- ! *Backfit Rule Considerations:* A discussion of why a backfit analysis need or should not be prepared for the proposed revision, sometimes including public comments on the Backfit Rule implications⁴⁴.
- ! *Staff Conclusion:* The staff's conclusion as to the application of the Backfit Rule to the proposed revision.

ANALYSIS OF BACKFIT RULE APPLICATION

GROUP I: ADOPTION OF NATIONAL STANDARDS

A. Changes to ensure compatibility with the HHS Mandatory Guidelines as revised in June 1994.

Section 26.24(f): MRO to report FFD policy violation in writing

Revision: This section would be revised to adopt a change to the HHS Mandatory Guidelines and require MROs to report FFD policy violations to licensee management in writing and in a manner designed to ensure confidentiality.

Purpose: Section 26.24(f) currently requires Medical Review Officers (MROs) to notify licensee management of the outcome of their reviews, but does not require the notification to be in writing. Requiring that all determinations of FFD policy violations be submitted to licensee management in writing would assist in preventing reporting errors. It would also ensure that licensees have documented evidence of the MRO's violation determination in all instances where the violation is challenged in an employment proceeding or is otherwise questioned. Although it is currently common practice for

¹ It should be noted that the Nuclear Energy Institute (NEI) prefaced some of its suggested changes and objections to particular rule revisions as requiring backfit analyses if its recommended change was not adopted. Hence, many of NEI's recommended substantive rule revisions that are actually unrelated to backfit issues are included as public comments on backfit issues.

MROs to submit such information in writing in a manner that ensures confidentiality, the staff believes that, due to the sensitive nature of the information, this should be explicitly required, as HHS does in its Mandatory Guidelines. It should be noted that the NRC staff has determined that it is unnecessary for the NRC to also require a written reporting of all testing results as HHS does as a tracking system to assure that all specimens have been tested and the results of all tests have been reviewed by the MRO. See revision to section 26.24(g) discussed next.

Licensee Cost Reduction/Increase: This revision makes explicit the industry's existing practice. As a practical matter it places no new or significant burden on licensees since it requires that only FFD policy violations, rather than all test results, be reported in writing to management.

Backfit Rule Considerations: NEI claimed this change was a backfit and commented that if this change were taken to extreme, FFD policy violators would be afforded with unescorted access while the written reports are being processed. The NRC staff concluded that NEI's concern that the production of a written report would extend the access time for the violator is unfounded. MRO's may still inform licensee management by telephone and the written report can be forwarded later. Furthermore, the written report can be a photocopy of Copy 4 of the standard custody-and-control form (see Chapter 4.F of the HHS medical Review Officer Manual). Section 2.6(h) of the HHS Mandatory Guidelines requires the MRO to report the results of all drug tests (positive and negative) in writing and in a manner to ensure confidentiality.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it is in conformance with HHS Mandatory Guidelines, increases the integrity of the program, and provides some additional protection to the privacy rights of employees.**

Section 26.24(g): Ensure all collected specimens are tested and results are reported

Revision: Sections 26.24(g) and 26.24(d) would be revised to explicitly require that licensees ensure that all collected specimens are tested and that laboratories report results for all specimen tests performed.

Purpose: This revision would clarify current implicit requirements, in Section 26.24(a), (b), (c) and (f) and Section 2.4(g) of Appendix A that collected specimens be tested, and in Section 2.7(g) of Appendix A that laboratories report test results. This revision would

be a companion to the change to section 26.24(f) (Group IA), and would be an adaptation of a change made to the HHS Mandatory Guidelines in June 1994, in which HHS required written reports on all specimens, both positive and negative, to ensure that all specimens had been tested and all results reviewed by the MRO.

Licensee Cost Reduction/Increase: No cost impact. Licensees currently use various procedures to ensure that laboratories test and report results on all specimens.

Backfit Rule Considerations: It is implicit in the rule that all specimens be tested and all results reported. This revision would make it explicit. There should be no change to licensee practice, but the language will now be consistent with HHS Mandatory Guidelines.

***Staff Conclusion:* This revision is not a backfit because it clarifies, but does not change, a current requirement. This revision is also consistent with the HHS Mandatory Guidelines.**

Section 1.2 of Appendix A: Delete definition of permanent record book

Revision: This is an administrative change in keeping with changes to sections 2.4(g)(9) and (24) of Appendix A. This change is addressed below in Group IA in the discussion of changes to those sections.

Section 2.4(d) of Appendix A: Courier signature not needed on chain-of-custody documents

Revision: Section 2.4(d) of Appendix A would be revised to clarify standard chain-of-custody procedures in accordance with current procedures defined by the HHS Mandatory Guidelines. The proposed revision, as published on May 9, 1996 (61 FR 21105), would have clarified that couriers need not sign chain-of-custody forms as long as the courier company has an appropriate tracking system. At this time, in light of actions taken by HHS (discussed under *Purpose*, below), the staff recommends that the rule be revised to incorporate the language in the HHS Mandatory Guidelines by stating that couriers are not required to sign the custody and control forms, (see changes to section 2.2(i) of the HHS Mandatory Guidelines at 59 FR 29920), and that custody accountability during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service.

Purpose: Standard chain-of-custody procedures called for in the current rule and practiced by licensees include attaching custody and control forms to each specimen [see sections 2.4(g)(26) and (27) of Appendix A] and placing specimen bottles in a securely sealed shipping container [section 2.4(i) of Appendix A]. Courier companies routinely sign for the shipping container and use their own internal tracking system to track shipping containers during shipment to the HHS-certified laboratory. The HHS-certified laboratory receives the secured shipping container and assures that the tamper evident seals on the shipping container are intact. Because specimens and their chain-of-custody forms are shipped together in sealed packages that would indicate any tampering during transit to the laboratory, couriers, express carriers, and postal service personnel do not have access to the chain-of-custody forms, and there is no need for such personnel to document the chain of custody for the package during transit. [Currently sections 2.4(g)(26) and (27) speak to chain-of-custody forms and the current section 2.4(i) requires that specimens be placed in securely sealed shipping containers.] This is in keeping with current licensee practice and standard forensic laboratory procedures and streamlines the specimen transportation process.

The revisions regarding chain-of-custody procedures at section 2.2(i) of the HHS Mandatory Guidelines (59 FR 29920; June 6, 1994) were made in response to a December 1993 arbitrator's decision ordering a Birmingham, Alabama bakery to reinstate a truck driver who had tested positive for drugs. The drug testing had been conducted under the DOT regulations in effect at that time. The arbitrator interpreted these regulations to require that all people who handle the specimen from the time of collection to final disposition be identified on the chain-of-custody form, including all courier personnel who handled the specimen during transportation to the laboratory. The arbitrator's decision was later upheld by a U.S. District Court (*Interstate Brands Corporation v. Local 441, Retail, Wholesale and Department Store Union*, U.S.D.C. for Northern Alabama, CV 93L-2694-S, March 31, 1994). On appeal, however, the District Court's decision was overturned ⁴⁵.

Subsequently, HHS issued revisions to its Mandatory Guidelines. Revised section 2.2(i) requires chain-of-custody documentation pertaining to particular specimens to be enclosed within each shipping container being used to transport those specimens to the

⁴⁵In December 1994, the U.S. Court of Appeals for the Eleventh Circuit reversed the District Court's decision and voided the arbitrator's decision [*Interstate Brands Corporation v. Local 441, Retail, Wholesale and Department Store Union*, 39 F.3d 1159 (11th Cir., 1994)]. The Court agreed that people involved in transporting sealed shipping containers containing specimens are not considered to be in the chain of custody and, therefore, need not sign chain-of-custody forms. The Court also acknowledged that tamper-evident seals on containers are sufficient guarantors of specimen integrity during specimen transportation.

drug-testing laboratory (59 FR 29920; June 6, 1994). Shipping containers are to be securely sealed to eliminate the possibility of tampering during shipment. That section furthermore explicitly states that courier personnel need not sign the testing agency's chain-of-custody form during transportation of the specimen package, the rationale being that the specimens are in a sealed package and any tampering would be evident and documented by the laboratory and that couriers would not have access to the form since it is inside the sealed package. DOT has also made similar revisions to its chain-of-custody procedures (59 FR 42996; August 19, 1994).

The revised HHS and DOT requirements are consistent with normal and acceptable chain-of-custody practice in federal workplace drug testing programs and in forensic science practice generally. It is normal practice in drug testing programs and forensic science to not require that all transportation personnel who have custody of specimens sign chain-of-custody forms accompanying those specimens. The internal shipping documentation and tracking systems of courier companies and the U.S. Postal Service have been found over many years to be reliable for the purpose of identifying those who handle and transport urine and blood specimens. Another reason for not requiring such identification is that it would mean forgoing the benefits (i.e., minimal risk of loss or damage) of having the chain-of-custody documentation enclosed in sealed shipping containers.

Licensee Cost Reduction/Increase: There will be no cost impact.

Backfit Rule Considerations: The Commission explicitly stated its intent in section 2.2(c) of Appendix A that specimens and associated paperwork (i.e., chain-of-custody documentation) would be placed in sealed shipping containers. [The current section 2.4(i) of Appendix A contains the more detailed directions regarding placing specimen bottles in shipping containers which are then securely sealed to minimize damage during shipment, etc.] This revision would make it clear that, in following these procedures, couriers are not required to sign individual chain-of-custody forms because both the specimens and those forms are sealed in tamper-evident shipping containers.

NEI argued that requiring courier companies to have such tracking systems would create a new burden that should be justified as a backfit. Requiring that licensees use courier companies with an internal tracking system as a practical matter adds no burden because all reputable courier companies already use such systems which have been found to be a reliable means of assuring the integrity of forensic evidence.

Staff Conclusion: This revision fits within the Backfit Rule's compliance exception. The Commission intended that chain-of-custody documentation was to be enclosed in the specimen shipping container. There was never any intent or need for specimen couriers to have access to and sign chain-of-custody forms where the courier has an appropriate tracking system for shipments. This revision is also consistent with the HHS Mandatory Guidelines.

Section 2.4(g)(4) of Appendix A: Eliminate requirement that tester request list of medications prior to specimen collection

Revision: Section 2.4(g)(4) of Appendix A would be revised to remove the requirement that tested individuals be asked to provide information concerning medications taken or administered in the past 30 days on the chain-of-custody (now referred to as custody and control) form.

Purpose: Uncontrolled public access to information about individual's prescriptions is a potential violation of the individual's privacy rights (which have been further strengthened by the Americans with Disabilities Act (ADA)). Furthermore, such information provided by the tested individual does not eliminate the need to do a confirmatory test on an unconfirmed positive screen test result, nor does it eliminate the need for the MRO to contact the individual after a confirmed positive laboratory test result. Information about prescription use can be used only when the MRO reviews a confirmed positive test result. It is at this stage, when this information can be conveyed by the tested individual directly and confidentially to the MRO, that information about medications the person may be using or has used becomes germane to determining whether a fitness-for-duty policy violation has occurred. The original requirement was permissive; the individual was not required to list the medications. When evaluating a test result, the MRO could not depend on the listing on the chain-of-custody form but would require evidence of a valid prescription beyond such a listing. Since it is undesirable to have any testing program or licensee personnel other than the MRO learning of the individual's use of medication, and since there is no need to ask for this information when the person submits a urine specimen, this section has been changed to preclude the collection of this information at that time. The individual can list the medications on his/her personal copy of the custody and control form. This change is consistent with the Federal Drug Testing Custody and Control Form (OMB No. 0930-0158) and Chapter 7 of the Urine Specimen Collection Handbook (Center for Substance Abuse Prevention (CSAP) Technical Report 12).

Licensee Cost Reduction/Increase: There is no cost impact.

Backfit Rule Considerations: This revision changes a requirement from the licensee being required to provide an opportunity to the donor to provide information concerning prescription and over-the-counter medications taken to requiring the licensee to not require such information. As such, it might be considered a backfit since it prohibits the licensee from requiring the donor to list medication used. However, it constitutes no burden on the licensee (rather it would reduce burden) and it can be considered to be a non-safety exception to conform with new legal standards. It is also a worthwhile change because it will protect employees' privacy rights in cases where there is no actual need for licensee management to have information about an employee's medications. In cases where this information is necessary for the MRO to determine whether a FFD policy violation has occurred, the rule provides an opportunity to convey the medication information to the MRO.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it is needed to conform with new legal requirements (the ADA) and it will protect employees' privacy rights. This revision is also consistent with the Federal Drug Testing Custody and Control Form (OMB No. 0930-0158) and Chapter 7 of the Urine Specimen Collection Handbook (CSAP Technical Report 12).**

Sections 2.4(g)(9) and (24) of Appendix A: Eliminate the requirement for a permanent record book

Revision: Sections 2.4(g)(9) and (24) of Appendix A currently require specimen collection site personnel to enter certain specimen collection information into a permanent record book. This section would be revised to eliminate this requirement.

Purpose: This revision is consistent with a change to the HHS Mandatory Guidelines that eliminates a previous requirement under those guidelines for a permanent record book. This revision would recognize that putting the information into a permanent record book is unnecessary.

Licensee Cost Reduction/Increase: Some undefined saving may be realized.

Backfit Rule Considerations: This would be a permissive relaxation of requirements for licensees. They can choose to continue to maintain a permanent record book or choose not to maintain such a book.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement. This revision is also consistent with the HHS Mandatory Guidelines.

Sections 2.4(g)(10), (15), (23) and (24) of Appendix A: Allow accompaniment or observation by person of same gender, other than a collection site person, during an observed collection

Revision: Various parts of section 2.4(g) of Appendix A would be revised to allow a person of the same gender as the donor who is not the collection site person to accompany or observe a collection.

Purpose: This revision would provide licensees with increased flexibility during situations when a collection site person of the same gender as the donor is not available. It would also conform the rule with the HHS Mandatory Guidelines.

Licensee Cost Reduction/Increase: Some undefined savings may be realized, e.g., because a worker does not have to wait for a collection site person of the same gender to be available.

Backfit Rule Considerations: This is a permissive relaxation for licensees. They can continue to require that a collection site person of the same gender accompany the individual for an observed test rather than to allow a same-gender person who does not work at the collection site to perform this function when the collection site person is not available.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement. This revision is also consistent with the HHS Mandatory Guidelines.

Section 2.4(g)(11) of Appendix A: Clarify fluid intake to assist in providing specimen

Revision: Section 2.4(g)(11) of Appendix A would be revised to clarify the amount of fluids an individual who has difficulty providing a specimen can consume during the waiting period. The revision would replace the parenthetical phrase "(e.g., a glass of water)" with "(e.g. normally an 8-ounce glass of water every 30 minutes, but not to exceed a maximum of 24 ounces)."

Purpose: That section currently permits licensees to give individuals (having difficulty in providing the required volume of urine) a "reasonable amount of liquid to drink for this purpose (e.g., a glass of water)". The staff understands that licensees have permitted employees to drink large quantities of water so that they can provide a specimen, believing that the large amount of water was reasonable. Reported experience in other industries indicates that the consumption of water by those unable to give a urine specimen should be limited to one 8-ounce glass of water every 30 minutes but not to exceed a maximum of 24 ounces. This rate is consistent with the recent revision to the HHS Mandatory Guidelines. According to the HHS Guidelines (59 FR 29911; June 6, 1994) one outcome of this change will be to reduce potential health risks that can occur from "water intoxication" due to consuming copious quantities of liquid in a short period. There is medical evidence that excessive intake of water (greater than one liter) over a short period of time may result in water intoxication, a condition in which there is an influx of water into the brain. Adverse health consequences may include lethargy, confusion and seizures. (*Acute Water Intoxication as a Complication of Urine Drug Testing in the Workplace*, Klonoff, D.C. and Jurow, A.H., JAMA: Journal of the American Medical Association 265(1):84-85, 1991.)

The revised rate would reduce the potential for hydration of specimens, a form of subversion of the testing process which results in false negative testing results. Therefore, the revision is also important to the protection of public health and safety. Since the current version of the standard is not achieving the purpose that the Commission had intended when it originally promulgated the rule, this revision is necessary to assure compliance .

Licensee Cost Reduction/Increase: There would be little cost impact. Minor changes to specimen collection procedures will have to be made.

Backfit Rule Considerations: Section 2.4(g)(11) currently allows testing site personnel to allow the tested person "a reasonable amount of liquid to drink for this purpose (e.g., a glass of water)" if he or she cannot produce the needed volume of urine. This revision clarifies the amount of fluid that should be considered reasonable (e.g. normally an 8 ounce glass of water every 30 minutes but not to exceed a maximum of 24 ounces) in such circumstances. The definition of a "reasonable amount" is in accordance with an explicit requirement in the rule that licensees take steps to assure that specimens are not adulterated or diluted (section 2.7(g) of Appendix A). Since there is ample evidence that excessive fluid intake is an effective and popular method of subverting the testing process (see NUREG/CR 5784, Chapter 6), this revision would assure improved compliance with that requirement. Because of the evidence that the current version of the standard may

not be achieving the purpose that the Commission had intended when it originally promulgated the rule, the revision is necessary to ensure compliance.

Staff Conclusion: This revision fits within the Backfit rule's compliance exception. This revision is also consistent with the HHS Mandatory Guidelines.

Section 2.4(g)(13) of Appendix A: Specify the temperature range for an acceptable urine specimen in whole numbers

Revision: Section 2.4(g)(13) of Appendix A would be revised to specify the temperature range for an acceptable urine specimen in whole degrees, rather than tenths of a degree.

Purpose: Section 26.24(g)(13) of the rule currently specifies the acceptable temperature range with a tolerance of a tenth of a degree. As HHS noted when it made this same change to its Mandatory Guidelines, such a narrow tolerance is unnecessary. This revision will avoid the need for licensees to measure temperatures to an unnecessary level of precision, and will be consistent with HHS.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: This would be a very insignificant administrative change. (Note that other changes to the provisions regarding specimen temperature are discussed in Group IIIA, below.) It could also be regarded as a permissive relaxation of a current requirement.

Staff Conclusion: This revision is not subject to backfit requirements because it is a permissive relaxation of a current requirement. This revision is also consistent with the HHS Mandatory Guidelines.

Section 2.4(i) of Appendix A: Clarify requirements concerning use of second, tamper-evident shipping container

Revision: Section 2.4(i) of Appendix A would be revised to clarify that both the shipping containers as well as the specimen bottles must be sealed to facilitate detection of tampering.

Purpose: By clarifying the current requirement that shipping containers must be sealed with tamper-evident seals, this revision would reduce the likelihood of undetected tampering. It would also minimize the confusion that some licensees have expressed

over the use of the word "container" which, at various places in the current rule, applies to both specimen bottles and shipping containers. The current sections 2.4(g)(20) and (22) require the use of tamper-evident seals on specimen containers (bottles). Likewise, section 2.4(i) currently requires that "specimens shall be placed in containers designed to minimize possibility of damage during shipment...and those containers shall be securely sealed to eliminate the possibility of undetected tampering." However, the current language of section 2.4(i) is unclear as to whether it applies to specimen collection bottles (as containers) or to the shipping containers. This revision would clarify that the shipping container must be sealed with a tamper-evident type of seal.

Licensee Cost Reduction/Increase: Because this is already a generally accepted forensic practice within the industry, this revision would have no cost impacts.

Backfit Rule Considerations: The Commission explicitly stated its intent in section 2.2(c) of Appendix A that there be clear written procedures concerning the use of a shipping container that can be sealed and initialed to prevent undetected tampering. This change is a clarification of the current section 2.4(i) requirement concerning the transfer (i.e., transportation) of specimens to the drug testing laboratory, which currently includes a requirement that "containers shall be securely sealed to eliminate the possibility of undetected tampering" and is fully consistent with current industry practices and the HHS Mandatory Guidelines requirement that shipping containers be sealed with tamper-evident seals. Some licensees have questioned whether both specimen bottles and shipping containers must be sealed to prevent tampering. This indicates that some licensees may not be sealing their shipping containers with tamper evident seals. This revision will clarify this requirement and bring these licensees into compliance.

***Staff Conclusion:* This revision fits within the Backfit Rule's compliance exception. This revision is also consistent with the HHS Mandatory Guidelines.**

Section 2.6 of Appendix A: Assure that training of licensee testing facility managers includes maintenance of chain of custody procedures

Revision: Section 2.6(a) of Appendix A would have been revised to conform requirements for training and experience of on-site testing facilities managers in chain-of-custody procedures to the HHS Mandatory Guidelines for managers of HHS-certified laboratories.

Purpose: This section currently lists several topics in which the on-site testing facility managers must be trained and experienced, particularly the procedures used by the

licensees, although chain-of-custody procedures are not currently specified among those topics. HHS and industry experience indicates that maintenance of chain of custody is critical to assuring the integrity of the steps in the collection and handling of specimens. HHS requires that HHS testing facility managers have training and experience in chain of custody. HHS originally included this requirement to address the problems with proper maintenance of chain of custody by laboratory analysts that were prevalent in the Federal drug testing programs. Although the NRC's FFD rule requires this training for HHS laboratory managers (in accordance with HHS guidelines) it neglects to specifically require training of on-site testing facility managers in chain-of-custody procedures. This revision would have ensured that personnel conducting on-site testing of specimens are skilled in the proper execution of chain-of-custody procedures, as HHS has done for laboratory personnel to ensure employees' rights were protected and legally defensible test results were maintained.

Licensee Cost Reduction/Increase: There would be no cost impacts.

Backfit Rule Considerations: The Commission expressed its intent in the current section 2.6 of Appendix A that licensee testing facility managers must be trained and experienced in the procedures that would be used, therefore, the inclusion of chain-of-custody procedures in this requirement is implicit. Upon further consideration, the staff has concluded that the current implicit requirement for training in chain-of-custody procedures is adequate and that this proposed revision should be withdrawn.

Staff Conclusion: Not applicable.

Section 2.7(f) of Appendix A: Conform the cutoff level for marijuana screening tests to the HHS Guidelines

Revision: Section 2.7(f) [currently section 2.7(e)] of Appendix A would be revised to reduce the screening cut-off level for marijuana from 100 nanograms per milliliter (ng/ml) to 50 ng/ml.

Purpose: This change is intended to maintain the existing level of marijuana detection embodied in the current FFD rule's 100ng/ml cutoff level, in light of changes in testing methodology. Marijuana has over 60 metabolites, of which one, Delta-9-tetrahydrocannabinol-9-carboxylic acid (THC), constitutes about 25 percent of the ingredients and is the metabolite of interest in confirmatory testing. Screening tests react to several of the metabolites; when the FFD rule was originally published in 1989, screening tests reacted to nearly thirty marijuana metabolites which were aggregated

together for purposes of determining whether the 100ng/ml level had been exceeded. Since then, the screening tests are now more specific for THC and react to fewer metabolites. With fewer metabolites being tested and aggregated, the THC concentration now needs to be far greater than it was in 1989 to produce a presumptive positive screening test result. A specimen that was a presumptive positive at the 100 ng/ml cut-off level in 1989 may not be a presumptive positive today under current screening tests. Therefore, the reduction in the screening cut-off level is needed to maintain the level of marijuana detection originally intended by the Commission.

This change would also ensure that licensees' specimens are tested by a process certified by HHS (any cutoff level different from the HHS-certified process mandated by the NRC or used by licensees is not certified by HHS and must be accompanied by appropriate licensee-monitored quality assurance (QA) measures). Currently, licensees can choose to use cutoff levels lower than those specified by HHS and to bear the additional costs associated with QA associated with such tests. If the NRC does not make this a required change, some licensees may be restricted by state regulations to using 100 ng/ml and, hence, be required to shoulder the costs of QA for using cutoff levels different from HHS, and have a less effective program. This revision would conform the minimum screening cut-off levels for marijuana established by the NRC to the screening cut-off levels set forth in the HHS Mandatory Guidelines and currently used by all Federal programs (including NRC's program for its employees).

Licensee Cost Reduction/Increase: Changing the marijuana cut-off level would create little or no cost impact. However, in some cases this may prevent a potential increase in cost that would occur if the licensee is required to use a cut-off level different from HHS standards, which are the standard cut-off levels used at HHS-certified laboratories.

Backfit Rule Considerations: The reduction of the marijuana cut-off level would be a modification of a current requirement that can no longer achieve the Commission's original purpose due to changes in the testing technology. The NRC adopted the 100 ng/ml cutoff level at a time when that level was the most appropriate for detecting and deterring marijuana use given the then current state of chemical testing technology. In the intervening nine years, testing technology has progressed such that a 50 ng/ml cut-off level is needed to provide an equivalent level of performance. HHS adopted the 50 ng/ml cut-off level four years ago. Because of the increased specificity of the immunoassay testing techniques for marijuana, the use of 100 ng/ml is not as effective at detecting THC as it was when the rule was first published in 1989. Hence, the change is necessary to maintain the original performance level of marijuana detection embodied in the current FFD rule.

Staff Conclusion: This revision fits within the Backfit Rule's compliance exception. This revision is also consistent with the HHS Mandatory Guidelines.

NEW: Section 2.7(f) of Appendix A: Prohibit non-instrumented testing devices

Revision: A revision to section 2.7(f) [currently section 2.7(e)] of Appendix A would prohibit the use of non-instrumented immunoassay testing devices in licensee FFD programs pending HHS approval of their use.

Purpose: When the proposed revisions were published in 1996, the Commission specifically requested comments on a number of issues concerning the use of non-instrumented screening devices. (See question 8 at 61 FR 21108 and the discussion of these issues at 61 FR 21125; May 9, 1996.) The staff has subsequently recommended this revision to this section, in response to public comments and actions taken by HHS. Congress has tasked HHS with reviewing the use of non-instrumented testing devices. Therefore, the staff has concluded that these devices are not yet sufficiently reliable for use in licensee programs. This revision would require licensee programs to wait until HHS has fully reviewed the accuracy and approved the use of these devices before incorporating these devices into licensee's FFD programs.

Licensee Cost Reduction/Increase: Prohibiting the use of non-instrumented testing devices would create no cost impacts, since no licensee is using such devices for compliance with Part 26 requirements at this time.

Backfit Rule Considerations: The rule is currently ambiguous as to whether non-instrumented testing devices can be used for screening testing. This is partially due to the fact that the HHS Mandatory Guidelines, the original basis for Appendix A to Part 26, do not address the use of these devices because HHS does not permit on-site testing. Also, HHS can control or prohibit the use of these devices through its laboratory certification program. This revision would clarify the status of these devices in response to several licensee inquiries as to whether their use is permissible under the rule. These technologies are technically "immunoassay tests" and therefore acceptable under the current rule but they do not currently meet the standards of the immunoassay tests available in 1989 to which the rule is referring. Allowing use of these testing devices would reduce the effectiveness of the rule, may produce a high number of false negative results and may facilitate subversion of the testing process, all of which are public health and safety concerns.

This revision is consistent with the intent of the HHS Guidelines, in that the National Laboratory Certification Program (which implement the Guidelines) prohibits the use of these non-instrumented devices at HHS-certified laboratories. The Staff believes that licensees' on-site testing procedures should also prohibit the use of such devices inasmuch as the on-site testing is the functional equivalent of testing by HHS certified laboratories.

Staff Conclusion: This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would prevent the use of testing devices that would reduce the effectiveness of licensees' FFD programs and increase the risk to public health and safety. This revision is also consistent with the intent of the HHS Mandatory Guidelines.

Section 2.7(g) of Appendix A: Modify the criteria for determining that a specimen is positive for amphetamines

Revision: The confirmatory test cut-off level table in section 2.7(g) [currently section 2.7(f)] of Appendix A would be revised to require that a methamphetamine confirmatory test result contain at least 200 ng/ml of amphetamine for the result to be reported as a laboratory-confirmed positive.

Purpose: The change to the confirmatory test cutoff level would conform the NRC's rule to a similar change made to the HHS Mandatory Guidelines on June 9, 1994 (59 FR 29908). This requirement was adopted by HHS to address false positive methamphetamine results that can be caused by chromatographic resolution problems in the confirmatory testing process.

Licensee Cost Reduction/Increase: There should be some unquantified saving that result from the reduction in false positive results and from the reduction in laboratory positives that are ruled negative after MRO review.

Backfit Rule Considerations: This change was in response to experience by HHS with regard to false positive results for amphetamines and is needed to maintain the validity of the methamphetamine detection standards set forth in the original rule. Reduction in false positives will reduce the number of employees who are incorrectly identified as positive for methamphetamine, thereby protecting employee's civil rights. This revision would require licensees to change their testing procedures in a way that will ensure against methamphetamine false positives. In so doing, it will be consistent with the Commission's intent to keep the rule current with changes in drug testing technical

advances. This revision will decrease the number of false positive results which will help protect employees; and enhance employees' acceptance of the FFD program which should enhance overall protection of public health and safety. This revision is consistent with the HHS Guidelines and was adopted by HHS to address false positive methamphetamine results. It may also reduce the licensees' costs of defending against private lawsuits brought by employees falsely identified as positive for amphetamines.

Staff Conclusion: This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule in order to further protect workers from false positive test results. This revision is also consistent with the HHS Mandatory Guidelines.

Section 2.7(g) of Appendix A: Require testing for d and l isomers of amphetamines

Revision: This revision would add a new section 2.7(g)(5) of Appendix A to stipulate that a test for *d* (dextro) and *l* (levo) isomers of methamphetamine be required for all positive tests for amphetamines. [One additional working day is provided the laboratory for processing specimens suspected of containing amphetamines by section 2.7(h)(1) (currently section 2.7(g)(1)).]

Purpose: Changes requiring *l* and *d* isomer testing would ensure proper implementation of HHS's Technical Advisory of March 11, 1991 and are required because some legal drugs (e.g., Vicks inhaler) contain amphetamine compounds that may yield a laboratory-confirmed positive for amphetamine use. Laboratory confirmatory tests for the *d* and *l* isomers are able to differentiate between compounds and to identify those positive test results that are the result of legal use of prescription or over-the-counter drugs. Many licensees have already been using this test as further confirmation of positive test results for amphetamines. This proposed revision would mandate the use of this test by all licensees and be consistent with current laboratory practice mandated by HHS in its Technical Advisory of March 11, 1991.

Licensee Cost Reduction/Increase: Any additional costs for *l* and *d* isomer testing would be minimal because it should be a current laboratory standard practice under the HHS laboratory certification program. These should be some unquantified savings that result from the reduction in false positive results and from the reduction in laboratory positives that are ruled negative after MRO review.

Backfit Rule Considerations: This change is in response to experience by HHS with regard to distinguishing between legitimate use of over-the-counter drugs as opposed to illegal use of amphetamines. This revision will decrease the number of false positive

results which will help protect employees and enhance employee acceptance of the FFD program which should enhance overall protection of public health and safety. This revision is consistent with the intent of the HHS Guidelines in that the National Laboratory Certification Program (which implements the Guidelines) mandate l and d isomer testing at address amphetamine testing problems.

Staff Conclusion: This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule in order to further protect workers from false positive test results. This revision is also consistent with the intent of the HHS Mandatory Guidelines.

Section 2.7(h) of Appendix A: Eliminate batch reporting of results

Revision: Section 2.7(h) of Appendix A would be revised to eliminate the requirement that test results must be reported in batches.

Purpose: This revision would increase the efficiency of the testing process by eliminating a practice that experience has shown to be unnecessary and costly. In fact the practice was stopped by the laboratories several years ago when HHS said it was no longer necessary.

Licensee Cost Reduction/Increase: Some unspecified savings may be realized.

Backfit Rule Considerations: This is a permissive reduction in burden. Licensees can continue to require batch reporting if they so choose. This revision is consistent with the HHS Guidelines in that batch reporting was discontinued several years ago and withdrawn as required by HHS in 1994.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement. This revision is consistent with the HHS Mandatory Guidelines.

Section 2.7(p) of Appendix A: Laboratory shall not have a conflict of interest with licensee's MRO

Revision: Revisions to section 2.7(p)(6) and section 2.9(b) of Appendix A would restrict the types of arrangements that can exist between the MRO and the HHS-certified laboratory or the operating contractor of an on-site testing facility. The rule would require that the MRO not be an employee, an agent of, or have any financial interest in the laboratory or on-site testing facility operator for which the MRO is reviewing drug testing

results. Similarly, the laboratory and on-site testing facility operator would be prohibited from having any relationship with the MRO that may be construed as a conflict of interest.

Purpose: These restrictions are consistent with recent changes to the HHS Mandatory Guidelines and the staff believes that they will assist in eliminating any conflict of interest between the MRO and the contract laboratory and on-site testing facility operator that may affect the impartiality and objectivity of the MRO in reporting testing deficiencies or errors to licensees.

Licensee Cost Reduction/Increase: Licensee costs would not be affected.

Backfit Rule Considerations: This revision would provide an important safeguard against actual or apparent conflicts of interest between MROs and HHS-certified laboratories. In doing so, the revision would fulfill the Commission's original intent that licensee FFD programs take measures to assure fair and accurate test results and protection of workers' rights. It would also serve to maintain the overall integrity of the testing program which, in turn, would promote worker acceptance of FFD requirements. This revision is consistent with the HHS Guidelines which prohibit conflicts of interest between the laboratories and the MRO.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would help assure fair and accurate evaluation of test results. This revision is also consistent with the HHS Mandatory Guidelines.**

Section 2.8(e) of Appendix A: Require that blind quality control materials meet standards for preparation, certification, and stability

Revision: Section 2.8(e)(1) of Appendix A would be revised to establish specific criteria for blind quality control specimens.

Purpose: Current requirements of section 2.8 of Appendix A set forth quality assurance (QA) and quality control (QC) requirements including the use of certified specimens and documentation of the precision of the testing methods and results. However, due to the lack of uniform standards for certification of blind control specimens, certification has been ineffective in assuring the use of acceptable blind quality control specimens. The invalid test results from poor quality blind control specimens lead to increased costs and lowered efficiency because additional tests and follow-up actions are necessary to validate the results of previously tested donor specimens. More importantly, the invalid

results may cause loss of confidence in the testing process. In order to eliminate these problems, this revision would explicitly state the criteria for blind quality control specimens in order to assure licensees comply with the standards for blind quality control materials and make the rule consistent with the HHS Mandatory Guidelines and current industry practice.

Licensee Cost Reduction/Increase: This revision could produce potential savings by avoiding the investigation and other actions required as a result of a bad quality control specimen.

Backfit Rule Considerations: Section 2.8 of Appendix A currently requires appropriate quality controls including the use of certified blind control specimens. However, experience has shown that certification has not been effective in assuring the use of high quality blind control specimens. The use of blind quality control materials are important QA measures to assure the integrity of the testing process. This requirement would provide specific criteria that blind performance specimens must meet. This revision is consistent with the HHS Guidelines in stating standards for blind quality control specimens.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would reduce the number of unacceptable test results from blind quality controls and, in turn, reduce the associated costs of investigating and correcting the errors. This revision is consistent with the HHS Mandatory Guidelines.**

Section 2.9(b) of Appendix A: MROs shall not have a conflict of interest with certified laboratories

Revision: This is a companion provision to section 2.7(p) of Appendix A, which states that certified laboratories shall not have a conflict of interest with MROs.

Section 4.1(b) of Appendix A: Note that licensees need to take appropriate measures when testing outside HHS certification process

Revision: Section 4.1(b) of Appendix A would be revised to add a cautionary reminder, upon the advice of SAMHSA, that the HHS national laboratory certification process does not cover practices outside the HHS Mandatory Guidelines and in such cases appropriate measures by licensees must be taken to assure that the reported test results are valid and defensible.

Purpose: This revision would provide additional clarification of current requirements set forth in section 2.8 of Appendix A concerning the QA/QC program and procedures which encompass all aspects of the testing process. This revision would respond to a request from HHS that licensees be cautioned that the QA/QC measures provided by the HHS national laboratory certification process does not include practices outside the HHS Mandatory Guidelines. These practices include testing at more stringent cut-off levels, testing for substances other than those set forth in the HHS Mandatory Guidelines, analyses of blind specimens for alcohol, etc.

Licensee Cost Reduction/Increase: There would be no cost impacts. The proposed change does not require any licensee action.

Backfit Rule Considerations: This is an administrative change, which essentially constitutes a warning to licensees that QA/QC measures under the HHS national laboratory certification program do not include practices outside the HHS Mandatory Guidelines. This was implicit under the existing Part 26; the change would make this explicit.

***Staff Conclusion:* This revision is not a backfit because it is an administrative matter.**

B. Changes to conform HHS Mandatory Guidelines revisions to the framework of the original FFD rule.

NEW: Sections 1.3, 2.7(f)(2), and 2.7(g)(4) of Appendix A: Future revisions

Revision: A new section 1.3 would be added to Appendix A, and section 2.7(f)(2) and 2.7(g)(4) would be revised to clearly state the Commission's intent to make future changes to Part 26.

Purpose: The addition of section 1.3 to Appendix A would adopt section 1.3 of the HHS Mandatory Guidelines, to ensure there is a clear statement that the Commission will make changes in the rule to (i) respond to the evolving disciplines related to substance abuse and employee fitness, (ii) ensure the field reliability and accuracy of drug assays, (iii) ensure the accurate reporting of test results, and (iv) ensure the integrity and efficiency of drug testing conducted under Part 26.

The revisions to the current sections 2.7(e)(2) and 2.7(f)(4) [redesignated as sections 2.7(f)(2) and 2.7(g)(4) in the revised rule] would clarify that the Commission may revise testing procedures and quality controls in addition to the substances and cut-off levels currently stipulated. These sections continue NRC adaptation of sections 2.4(e)(2) and 2.4(f)(2) of the HHS Mandatory Guidelines.

Licensee Cost Reduction/Increase: No cost impact.

Backfit Rule Considerations: The Commission explicitly stated in the current sections 2.7(f)(2) and 2.7(g)(4) that it would make changes in response to industry experience and changes made by HHS to its Mandatory Guidelines as advances in technology, additional experience, or other considerations warrant. These revisions are needed to ensure that NRC and licensee policy and budget planners recognize that future revisions to Part 26 may be necessary. These revisions do not provide a basis for a "compliance backfit" finding in a future rulemaking amending these FFD requirements. They merely announce intent and do not establish any requirements. Accordingly, any future changes constituting backfits would have to be justified with respect to costs and benefits, or a "documented evaluation" provided which discusses the applicability of one or more of the three exceptions in 10 CFR 50.109(a)(4). These revisions parallel similar provisions in the HHS Mandatory Guidelines and DOT regulations.

***Staff Conclusion:* These revisions are not subject to backfit requirements because these are administrative changes. These revisions are also consistent with the HHS Mandatory Guidelines.**

Sections 26.24(d)(1) and (g): Require licensees to ensure that all collected specimens are tested and results reported

Revision: Various proposed editorial changes to section 26.24(d) would leave its requirements essentially unchanged from the amendment to this paragraph published by the NRC on August 26, 1991 (56 FR 41922). There are no relevant revisions to (d) or (g) that relate to the change described in the above heading that were not discussed under section 26.24(g) in Group IA of this document. The inclusion of this section here is a redundancy.

Section 2.4(g)(11) of Appendix A: Reduce required minimum quantity of each urine specimen from 60 ml to at least 30 ml (Where licensee chooses to test on site, split specimens, or to test for additional drugs, more than 30 ml will be necessary)

Revision: Section 2.4(g)(11) of Appendix A would be revised to reduce the required urine specimen quantity from 60 milliliters (ml) to 30 ml for the primary specimen and, when split specimens are collected, to require the collection of an additional 15 ml. The total quantity to be collected must take into account all analysis and reanalysis required by the licensee's program.

Purpose: The revision would conform this section with recent revisions to the HHS Mandatory Guidelines. HHS-certified laboratories require only a few milliliters for testing. A 30 ml sample is sufficient in volume for both immediate testing and for the retention of a portion of the primary specimen for reanalysis, if necessary. If licensees provide for a split specimen, an additional 15 ml is required. Because some licensees conduct on-site testing and test for additional drugs, they may need to collect an additional volume to meet these needs. A provision has been added to the rule to specify that if the donor is not capable of providing sufficient volume, the specimen is used in the following order of priority: testing at the HHS-certified laboratory, split specimen, and on-site screening tests. Since the rule only requires 30 ml for testing at the HHS certified laboratory plus an additional quantity if the licensee tests for additional drugs, this priority of use assures that specimens are sufficient to meet minimal NRC requirements, but not all of the licensee's program needs will be used appropriately.

Licensee Cost Reduction/Increase: Some unquantified cost reduction would result from the reduction in volume for the primary specimen since fewer donors will have difficulty providing an adequate specimen, thus reducing the time these employees are away from work.

Backfit Rule Considerations: The revision would relax current requirements. Licensees can collect 30 ml or 45 ml instead of 60 ml. Licensees could still choose to collect 60 ml in all cases. This revision is also consistent with the intent of the HHS Guidelines to reduce the required minimum quantity of each urine specimen from 60 ml to at least 30 ml. An additional 15 ml is required by HHS when split specimens are collected. Because additional urine would be needed for onsite testing and testing for additional drugs, the staff recommends that the NRC require that the total volume collected must be predetermined by each licensee to meet its unique needs.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement. This revision is consistent with the intent of the HHS Mandatory Guidelines.

NEW: Section 2.4(g)(11) of Appendix A: Require partial specimens to be shipped separately and not combined

Revision: Section 2.4(g)(11) of Appendix A would be revised to state that partial urine specimens must not be combined, but must be packaged separately before being sent to the licensee's testing facility or HHS-certified laboratory for analysis (the separately-packaged specimens could be shipped together in the same shipping package).

Purpose: This revision would eliminate a potential for subversion of the testing process by individuals who provide only partial specimens. Section 2.4(g)(11) of Appendix A currently requires that, if a person produces less than the required amount of urine (a partial specimen), additional urine is to be collected in separate containers until the total required amount has been collected. The partial specimens are then to be combined into one container for shipment for testing. The Commission had two reasons for originally adopting this requirement, which was a departure from the HHS Mandatory Guidelines. First, the Commission was aware that producing a series of partial specimens could be used as a technique to subvert the testing process by delaying the collection of a complete specimen. Without the Commission's original requirement to combine partial specimens, those wishing to subvert the testing process could provide only partial specimens (which would have been disposed of under the HHS Guidelines) and, since a "complete" specimen was never provided, the employee would not be tested. Also, the delaying tactic would enable the employee to lower the concentration level of any drugs through hydration or metabolism over time. At the time the rule was adopted, the Commission was also under the impression that the HHS-certified laboratories needed at least 60 ml of urine from each donor to complete the testing process. Consequently, the Commission's second reason for requiring the combining of partial specimens was to ensure that laboratories would have enough urine to fully test the specimens in situations where donors who were not trying to subvert the testing process were able to produce only multiple partial specimens.

While the current requirement to combine specimens was intended to cope with one type of subversion tactic, i.e., delaying the collection of a specimen, experience with other types of subversion tactics (adulteration, dilution, and submission of surrogate samples) indicates that combining specimens would destroy evidence and that a testing strategy which is the reverse of the current requirement is needed. For example, in 1992, a

licensed operator at San Onofre submitted partial specimens which were kept separate and tested; the specimens had cocaine just below cutoff levels which the MRO declared positive (see Appendix F of NUREG-/CR-6470). The revision to section 2.4(g)(11) would protect against both subversion tactics, by requiring collection site personnel to retain all partial specimens in separate specimen bottles and to send them⁴⁶ to the licensee testing facility or HHS-certified laboratory to be tested separately. The first partial specimen, along with any additional partial or complete specimens, should be tested like all other specimens for validity and for the presence of drugs. Licensees will be advised to make sure that their specimen collection procedures should not contaminate the specimens (which, is a risk if the specimens are combined). After the laboratory has determined specimen validity and that all specimens came from the same person, testing can continue. (It should also be noted that the drug testing community's experience of finding that one or more specimens in a series of partial urine specimens, supposedly submitted by the same person, have sometimes been found to have originated from other than the person being tested is another reason for requiring each partial specimen to be analyzed separately.)

In summary, this revision is necessary to augment the rule's protections against subversion. The change is also consistent with a public comment requesting such a change.

Licensee Cost Reduction/Increase: Licensees will probably incur additional costs to package and test the partial specimens separately. The staff estimates that, on average, each licensee would have to ship and test an additional 161 specimens each year (156 specimens plus 5 blind test specimens). This would result in an additional annual industry-wide cost of approximately \$596,000.

Backfit Rule Considerations: The revision is one of several rule changes aimed at achieving the long-standing goal of reducing the chances of successful subversion of the testing process. From its inception the FFD rule has very clearly required licensees to take measures to prevent testing subversion. For example, section 2.4(g) of Appendix A requires licensees to take precautions to ensure that specimens are not adulterated or diluted and that authentic specimens are obtained. The combining of partial specimens that was originally included in the NRC's FFD rule was a departure from the HHS Mandatory Guidelines to thwart delaying tactics of donors who provided partial specimens as a subversion technique. This particular revision will provide clarification and guidance

⁴⁶The licensee need not conduct on-site testing, especially if the volume in the partial specimen precludes testing at both the licensee's on-site facility and the HHS-certified laboratory.

as to a better means for licensees to achieve this goal and prevent contamination of specimens. This revision is consistent with the Commission's initial intent in addressing subversion techniques during the collection process and the intent of the HHS Guidelines to take precautions to ensure that specimens are authentic and not adulterated or diluted during the collection process. The HHS approach of disposing of partial specimens and continuing to collect until a "complete" specimen is provided was not accepted during the original rulemaking and is still not acceptable, as discussed above.

Staff Conclusion: This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would strengthen the rule's protection against testing subversion by eliminating a current means of subversion and reduce the current potential for contamination or other error during the combining of specimens as currently required. This revision represents an improvement on the HHS Mandatory Guidelines, since those Guidelines fail to guard against a known subversion tactic.

Section 2.7(e) of Appendix A: Validity of specimens, i.e., tests for adulteration and dilution at HHS-certified laboratory

Revision: A proposed new section 2.7(e) of Appendix A would require the testing of all specimens to determine their validity and the special processing of those specimens found to be of questionable validity. Section 2.7(e) contains several separate requirements. The requirements pertaining to the validity testing of specimens at HHS-certified laboratories are discussed here. A related part of the proposed new section 2.7(e) would require special processing of specimens of questionable validity at HHS-certified laboratories. This is discussed in Group IIA. The remaining part of the new section 2.7(e), which would require licensees that conduct on-site testing to test for specimen validity at their testing facilities, is discussed in Group IIIA.

The proposed revision would enhance the effectiveness and reliability of licensee FFD programs by requiring HHS-certified laboratories to determine the validity of all specimens they receive from licensees. At a minimum, the required testing would include analysis of acidity/alkalinity (pH), creatinine levels, nitrites, and, in some circumstances, specific gravity (SG). A second revision to this section would make explicit the currently implicit requirement that HHS-certified laboratories are to report the results of these specimen validity tests to the MROs.

Purpose: This adaptation of recent changes to the HHS Mandatory Guidelines and of standards set forth in HHS' National Laboratory Certification Program (NLCP) Program

Document #35 would require tests to detect evidence of adulteration and dilution, thereby reducing the potential for subversion of the testing process. Many licensees already conduct this type of testing to detect and discourage subversion. The requirements concerning specimen validity testing at the HHS-certified laboratories is intended to bring other licensees into compliance. The second revision would address licensees' concerns that the rule does not explicitly require the laboratories to report the results of specimen validity tests, such as tests for pH, specific gravity, and creatinine, to the extent these tests are performed. (Some laboratories have been reticent about providing this information because it is not explicitly required.)

The first revision would explicitly describe the measures that HHS-certified laboratories must take to detect specimen adulteration and dilution, the two principle means of testing subversion which are recognized by national authorities as a serious challenge to the effectiveness of drug testing. Recent DOT experience with adulterated specimens has caused HHS to examine laboratory practices in this area. HHS determined that only four of its certified laboratories were performing comprehensive specimen validity testing; many were doing some sort of specimen validity tests. After reviewing the data, HHS concluded that there are 30,000 adulterated specimens and 120,000 dilute specimens processed each year under the federally certified programs. An MRO service reported that during October 1995-February 1996, HHS-certified laboratories that the service used reported that 385 specimens were "unsuitable for testing." Further testing directed by the MRO service determined that 85.4% were confirmed as adulterated (specific adulterant identified) or positive for a specific drug. To address this problem HHS has recently published NLCP Program Document #35, pending rulemaking by HHS and DOT, that establishes standards for specimen validity testing that includes testing for creatinine, SG, pH, and nitrites.

These HHS findings are confirmed by similar experience among NRC licensees. Licensees have encountered various practices, such as adulteration and dilution, by substance abusers to avoid detection. Numerous examples of cases involving invalid specimens due to subversion are described in Appendix F to NUREG/CR-6470. This revision would require licensees that have not already done so to adopt practices that minimize the vulnerabilities in the testing process that have been exploited. One of these measures, already explicitly authorized under the current rule in sections 2.4(g) and 2.7(d), is to determine specimen validity. (The NRC requested comments on whether these tests for determining specimen validity should include tests for SG, pH, creatinine, and other tests for adulterants.)

The new section 2.7(e) revisions discussed here and in Groups IIA and IIIA would collectively require that urine specimens be tested for SG, pH, nitrites, and creatinine. The information developed during these procedures would enable the MRO to make an accurate determination of whether a specimen of questionable validity has actually been adulterated or diluted. If the specimen has been adulterated or "heavily" diluted (i.e., beyond standards for "marginal" specimens as set forth in the rule), specimen validity test results would indicate an obvious attempt to subvert the testing process and testing for drugs would not be necessary (and may be useless). If the specimen is "moderately" diluted, with no drugs detected, and the worker's health habits reveal consumption of quantities of liquids consistent with the test results, the MRO would determine that there was a legitimate reason for the dilution and that there had been no attempt to subvert the testing process. If drugs are detected, the MRO would conclude that the worker has attempted to subvert the testing process. If the MRO cannot determine if the specimen is valid or invalid another specimen would be collected, as currently required by section 2.4(f) of Appendix A.

Licensee Cost Reduction/Increase: Because some HHS-certified laboratories have indicated that testing for adulteration and dilution would be a "cost of doing business," most licensees may not encounter increased costs for having their laboratory conduct such tests. One HHS-certified laboratory speculates that it may increase the cost of testing by approximately \$1 per specimen. In the case of those licensees whose laboratories do charge extra for such testing, these ongoing costs are expected to be reduced due to fewer ambiguous findings requiring recollection of specimens.

Backfit Rule Considerations: The NRC's long-standing intent that licensees test specimens to assure their validity as one means of preventing subversion of the testing process is clearly stated in the FFD rule and in the 1989 Federal Register notice by which the NRC promulgated this rule. For example, the current section 2.4(g) of Appendix A requires that "Licensees shall take precautions to ensure that a urine specimen is not adulterated or diluted ... [and] ... that authentic specimens are obtained ...". The current section 2.7(d) provides that "Special processing may be conducted to analyze specimens suspected of being adulterated or diluted (including hydration). Any evidence of adulteration or dilution, and any detected trace amounts of drugs or metabolites, must be reported to the Medical Review Officer." In its 1989 Federal Register notice (at 54 FR 24475; June 7, 1989), the Commission noted that Appendix A to the rule contains "procedures for the collection of samples to ensure the integrity of the samples and limit opportunities for sample tampering." The requirements for validity testing and the special testing of questionable specimens in the proposed section 2.7(e) are specific means by

which licensees can "take precautions" and conduct the kinds of "special processing" that are needed to ensure the integrity of the testing process.

While several licensees have already adopted specimen validity testing and limit of detection (LOD) testing of questionable specimens, others have not. The revision would assure that these licensees that are not now testing specimens for validity will do so, thereby creating consistency across licensees on this very important issue.

NEI recommended that this revision not be made. Instead, NEI recommended that the details of how licensees can determine specimen validity be published in some kind of supporting document or industry-developed guidelines rather than in Appendix A. NEI contended that this approach would avoid locking in a procedure that may need to be changed after implementation experience. In other words, NEI apparently accepted the need to elaborate upon the current general specimen validity testing requirement as a means of preventing subversion of the testing process. It disagreed, however, on the best means of doing so.

The NRC staff believes that the proposed regulatory approach would better address the NRC's regulatory needs and be consistent with the uniform Federal position on specimen validity testing resulting from DOT's experience discussed above. A rule establishes a well defined public policy which the courts have recently demonstrated to be necessary in matters such as this. See Niagara Mohawk Power Corporation v. IBEW (1998 WL 227981). Those licensees that are not currently complying as fully as needed to detect and discourage subversion of the testing process should be given direction and minimum standards to assure specimen integrity that is more explicit than is prescribed in the current rule. As described above, HHS has come to a similar conclusion. It has already revised its requirements accordingly and is currently developing an even stronger and more explicit directive that would require its certified laboratories to conduct validity testing.

It should also be noted that HHS has recently published its Program Document #35 which establishes standards for HHS-certified laboratories to test specimens for adulteration and dilution. The NRC staff believes that this HHS action provides ample evidence of the need for such validity testing in NRC licensees' FFD programs. This revision is consistent with the intent of the HHS Guidelines in that the National Laboratory Certification Program (which implements the Guidelines) mandates specimen validity testing that includes tests for creatinine, specific gravity, pH, and nitrites.

Staff Conclusion: This revision fits within the Backfit Rule's compliance exception and is necessary to achieve an original purpose of the rule to "ensure that a urine specimen is not adulterated or diluted ... [and] ... that authentic specimens are obtained ...". This revision is also consistent with the intent of the HHS Mandatory Guidelines.

Section 2.7(f) of Appendix A: Permit multiple screening tests only in certain limited situations [formerly: Permit multiple immunoassay (screening) tests for the same drug or drug class]

Revision: A new section 2.7(f)(3) of Appendix A would permit licensees to conduct multiple screening testing in four limited situations: 1) on unconfirmed positives for amphetamines, 2) on specimens when needed to reduce the effect of possible cross reactivity due to structural analogs, 3) on specimens where a valid analytical result cannot be obtained using one particular immunoassay technique due to interference in the assay, or 4) on unconfirmed positive specimens that appear to have a high concentration of drugs or metabolites to determine an appropriate dilution requirement for confirmatory analysis.

Purpose: This revision responds to concerns raised by many licensee staff who learned that their laboratory was routinely using multiple screening tests on all specimens as a cost-cutting measure (costs are reduced by reducing the number of specimens that are subjected to more costly confirmation testing). Multiple screening is the practice of using different screening technologies in succession on a specimen until a negative result occurs, and testing remaining specimens using gas chromatography/mass spectrometry (GC/MS). Multiple screening in this manner should not be routinely used in testing for drugs because it can significantly increase the incidence of false negative test results⁴⁷. These screening tests have improved since the study, however, the staff is not aware of any more current false negative data. The current rule requires that all specimens that test positive on a HHS laboratory screening test be confirmation tested using GC/MS techniques. (Section 2.7(g)(2) [currently section 2.7(f)(2)] states "All urine samples identified as presumptive positive on the screening test performed by a HHS-certified laboratory must be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cut-off values listed in this paragraph for each drug....".) The revision

⁴⁷A 1991 National Institute of Justice study compared the results of four different screening tests to GC/MS results on 2,668 urine specimens collected from parolees and arrestees. The results varied by test and by drug, the range of false negatives for marijuana was 29-41%, cocaine was 18-26%, opiates 15-18%, amphetamines 2-13%, and PCP 6-21%.

responds to an HHS modification to its Mandatory Guidelines made in 1994 to allow multiple screening tests (with no GC/MS testing if one screening test is negative) in certain cases. HHS made this change to reduce the potential for cross reactivity due to structural analogs encountered during screening tests for amphetamines, and to address other unique testing problems. The intent of this revision, therefore, is to give licensee FFD programs greater flexibility by authorizing multiple screening when specimens appear to contain amphetamines and for other specific purposes when there is a valid technical basis, without allowing the original standards of the rule to be undermined. The economically motivated changes in laboratory practices over the past few years that have caused several licensees to express their concern requires that the NRC specifically prohibit multiple screening tests except in the rare cases of unique problems encountered in testing for amphetamines and other limited applications as now provided for by the HHS Mandatory Guidelines.

This change supplements the current screening testing requirements of section 2.7 [currently section 2.7(e)] by clarifying that multiple screening testing without GC/MS testing is permitted only in specific cases as a measure to maintain the standards specified in the original rule. It also contains a permissive change to allow, but not require, multiple screening tests in some cases where it is suggested by HHS Mandatory Guidelines.

Licensee Cost Reduction/Increase: There may be a slight increase in cost if the laboratories had passed the savings realized through multiple screening on to the licensee.

Backfit Rule Considerations: Section 2.7(f)(2) currently requires that all specimens that test positive on a screening test performed by a HHS-certified laboratory be confirmation tested using GC/MS. Licensees have reported that many laboratories are using multiple screening tests rather than confirmatory tests following a presumptive positive test, in violation of section 2.7(f)(2). HHS has decided to permit this practice in limited situations to address specific testing technology problems in section 2.4(e)(4) of the HHS Mandatory Guidelines (59 FR 29908; June 9, 1994 at 29921). This change would assure compliance with the Commission's original intent and adopt, with some modification, similar requirements regarding multiple screening tests set forth in the HHS Mandatory Guidelines. This revision, which was developed in conjunction with HHS, would better convey the intent of those HHS requirements. This revision is consistent with the intent of the HHS Guidelines to permit multiple immunoassay (screening) tests for the same drug or drug class. Because the language in the HHS Guidelines could be interpreted as endorsing multiple screening tests for all drugs as a routine practice (which would

increase the number of false negative testing results) and because HHS staff emphasized that this procedure should only be applied to amphetamines (where structural analogues cause specificity problems) and special circumstances where valid results cannot be obtained, the staff recommends that the NRC adopt clarifying language, which was provided by HHS.

NEI stated that it is aware of improved immunoassay technology that can be used for second screening tests. This technology would be used to differentiate between true amphetamine positives and numerous legal medications that could interfere with testing results. NEI contended that such second screen tests do not lead to an increase in false negatives. NEI argued that, by limiting the opportunities for multiple screen testing, this revision would increase licensee costs and lengthen the turn-around time to get test results. With respect to NEI's first contention, the Staff notes that the proposed change would permit licensees to use second screening tests for amphetamines, which is the only drug for which NEI cited improved immunoassay technology. NEI did not identify other immunoassay technology capable of accurately differentiating between illegal and legal versions of the drugs, such that second screening is justified. With respect to NEI's contention that second screening tests do not increase false negative results, a licensee reported on July 1, 1998, a false negative on a blind performance test specimen had resulted from the use of a second screening test that was more specific for amphetamines and methamphetamines. The proposed rule change provides increased flexibility to licensees to use second screening tests in appropriate circumstances (thereby reducing licensee costs), but prohibits second screening tests in situations where their efficacy (i.e., incidence of false negatives) has not been established.

***Staff Conclusion:* This revision fits within the Backfit Rule's compliance exception. It also provides increased flexibility to address specified testing problems as intended by the change to HHS Mandatory Guidelines. This revision is also consistent with the intent of the HHS Mandatory Guidelines.**

NEW: Sections 2.7(g)(2) and (5) of Appendix A: Modifications to opiate testing requirements

Revision: Sections 2.7(g)(2) and (5) of Appendix A would be revised to allow licensees to test for 6-acetylmorphine (6-AM) only when the morphine concentration found in confirmatory testing exceeds 2,000 ng/ml. This revision would adopt a similar change that HHS made to its Mandatory Guidelines on September 30, 1997 (62 FR 51118).

Purpose: This section currently requires licensees to include a test for 6-AM (which was formerly referred to as 6-monoacetylmorphine) in all confirmatory testing for opiates. The 6-AM test allows the MRO to differentiate between a number of common legal opiates or opiate-like synthetic drugs and heroin. Research conducted by HHS indicates that requiring 6-AM testing as part of all confirmatory testing for opiates is unnecessary because a vast majority of 6-AM tests that ultimately result in confirmed positive test results have morphine concentrations of at least 2,000 ng/ml. Therefore, HHS concluded, and the staff agrees, that these results indicate that testing for 6-AM is necessary and practical only in cases where the morphine concentration is at or above that elevated level.

Licensee Cost Reduction/Increase: By reducing the number of 6-AM tests that licensees must conduct, this revision will result in unquantified savings.

Backfit Rule Considerations: Licensees will still have the option to test for 6-AM in all their confirmatory testing for opiates. It is unlikely they will do so, however, given the savings that would result from eliminating the unnecessary testing for 6-AM when the morphine level is below 2,000 ng/ml. Those licensees that reduce their 6-AM testing will obtain a reduction in testing costs due to this revision. This revision concerning 6-AM is consistent with the HHS Guidelines. NOTE: Commenters did not support raising the opiate cutoff level as HHS did.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement. This revision is also consistent with the HHS Mandatory Guidelines.**

Section 2.7(k) of Appendix A: Clarify that testing of split specimens is not subject to specific cut-off levels and allow three days for forwarding split specimens for testing (formerly: Clarifications to split specimen collection and dispatch procedures and laboratory selection)

Revision: The original intent of section 2.7(k) (currently section 2.7(j) of Appendix A) would be clarified with regard to the applicability of the quantitation of test results to split specimens. Specifically, the revised section would stipulate that the quantitation of the result of a test of a split specimen is not subject to a specific cut-off requirement but instead must only provide data sufficient to confirm the presence of the drug or metabolite. This adopts the same requirements that are applicable to the retesting of primary specimens found in section 2.7(i) of the current rule.

The staff is also proposing a new revision to this section that was not included in the Commission's 1996 Federal Register notice. This revision would allow licensees three week days (instead of the current one day period) in which to forward split specimens for testing.

Purpose: The first revision is a clarification made in response to difficulties NRC staff and licensees have had with testing laboratories. Staff have had to negotiate with HHS-certified laboratory personnel on several occasions regarding provision to licensees of quantitation of test results due to lack of clarity in the current wording of the rule. This revision would explicitly state the laboratories responsibilities in the testing of split specimens.

The newly proposed revision that would allow HHS-certified laboratories three weekdays in which to forward split specimens to another laboratory for testing recognizes the practical realities of these situations. In retrieving the split specimens from storage and sending them to another laboratory, the original HHS-certified laboratory must go through several steps and maintain normal chain of custody while doing so. Experience has shown that taking the steps necessary to forward specimens cannot reasonably be done in one day, as this section currently requires.

Licensee Cost Reduction/Increase: There would be no significant cost impact.

Backfit Rule Considerations: The first revision is a clarification of existing requirements in that it would apply the same standards regarding the quantitation of test results to split specimens that section 2.7(i) currently applies to the retesting of primary specimens. The newly proposed revision would relax the current same-day requirement by allowing the testing laboratories up to three week days to forward split specimens for testing.

NEI asked the Commission to clarify in this section of the rule that lack of a split specimen shall not affect employment actions based on retests of primary specimens. This was in reference to the fact that whether urine specimens are split into primary specimens and secondary specimens that would be used by the employee to appeal a violation is left to licensees' discretion. NEI also requested that the NRC change the current requirement that licensees forward split specimens to a HHS-certified laboratory for testing on the day they are requested to do so by the employee in question. Instead of this same-day requirement, NEI asked that licensees be allowed up to three days to forward split specimens.

The first issue raised by NEI has no bearing on whether or not this revision is a backfit. The NRC is not proposing any change to the current discretionary status of specimen splitting. Nor is it proposing any new or altered wording regarding whether lack of a split specimen should have an effect on employment actions based on primary specimen test results. In response to NEI's request, however, the staff believes that there is no good reason for the Commission to take an explicit position on this issue in the rule. Whether or how lack of a split specimen should be considered in employment actions should be left up to the adjudicators in those actions. Adjudicators should be free to give this fact whatever weight appears appropriate in the particular circumstances. In any case, there is no proposed rule change on this issue that could constitute a backfit.

Insofar as NEI's second request is concerned, the staff now recommends that this requirement be revised, in line with NEI's suggestion, to allow licensees three business days in which to forward split specimens for testing. This newly proposed change is a permissive relaxation. This revision is consistent with the intent of the HHS Guidelines to provide quantitative test results without cutoff levels when testing split specimens and that the testing of split specimens occur within a reasonable period after it is requested.

Staff Conclusion: The first revision is not a backfit because it clarifies, but does not change, a current requirement. The second revision, which provides additional time to forward a split specimen for testing, is not a backfit because it is a permissive relaxation of a current requirement. These revisions are also consistent with the intent of the HHS Guidelines.

Section 2.7(k) of Appendix A: Minimum time for requests by individuals to have split specimen tested at another HHS-certified laboratory

Revision: This revision to section 2.7(k) of Appendix A would be revised to provide an opportunity for a tested individual to make a timely request for a test of the split specimen after having been notified of a FFD violation.

Purpose: Section 2.7(k) [section 2.7(j) in the current rule] of Appendix A, which permits licensees to "split specimen," currently requires the licensee to forward the split specimen for testing at the tested individual's request. There is no time limit for the individual to make the request; the individual could make the request several weeks or months later. Although such specimens are either chilled or placed in frozen storage (see section 2.7(c) and 2.7(i) [section 2.7(h) in the current rule] of Appendix A, there is still some specimen degradation (loss of analyses and metabolites which results in a false negative result). Although degradation of frozen or chilled specimens is not as rapid as in specimens

which are not chilled or frozen, the possibility of unacceptable degradation warrants some limit on the time period for requesting tests of split specimens. The question then becomes how much time should be permitted for an individual to request a retest. The HHS Mandatory Guidelines, in establishing a timeliness standard for federal employees, required that a request to test the split specimen must be honored if it is made within 72 hours of the donor being notified of the positive test result. HHS staff has confirmed that this timeliness standard was strictly a policy decision and that there was no technical basis, such as concern for specimen degradation, in establishing that standard. The proposed rule provided a minimum of 72 hours for a tested individual to request a test of the split specimens, which was inconsistent with the HHS Guidelines. The basis for the proposed rule was to ensure that individuals be provided with sufficient time to request such testing, and that an explicit time period would minimize uncertainty with respect to the appropriate period for allowing such test requests.

Upon reconsideration of this matter, the NRC staff recommends that the Commission adopt a more flexible standard that will protect both the licensee's and employee's interests. The staff recommends that licensees be given the authority to establish appropriate time limits for requesting split specimens consistent with the licensee's experience (e.g., notification of test result just before a long shift break, before a long holiday weekend, the individual out) but without specifying any specific time period. This would permit licensees to establish an appropriate period, but that there be a reasonable basis for the period. While an MRO may honor a request made beyond the licensee-established period, the MRO is not required to do so. The staff believes that providing such flexibility to the licensees outweighs any advantage from having a rule-prescribed period; the requirement that the period be "reasonably established" provides assurance that the licensee does not arbitrarily establish an inordinately-short period.

As described below in Group IB, the current wording of section 2.9(e) establishes the related process by which employees can request reanalysis of their primary specimens. According to the current wording of section 2.9(e), employees must make a "timely request" for such reanalysis. This proposed revision to section 2.7(k) and the revision to section 2.9(e) would establish consistent timeliness standards between these two similar requirements.

Licensee Cost Reduction/Increase: This revision would have no cost impact.

Backfit Rule Considerations: This revision would provide a licensee-established period for tested individuals to request that their split specimens tested for purposes of appealing an FFD violation. It would also create consistency between, and thereby clarify, the two

related processes under which employees can request the testing of their split specimens in section 2.7(k) and the retesting of their primary specimens in section 2.9(e). This revision is consistent with the intent of the timeliness standard set forth in the HHS Guidelines.

Staff Conclusion: This is an worthwhile revision that the staff recommends be consider for adoption as an exception to the Backfit Rule because it establishes a requirement concerning the timeliness of the tested individual's request for testing the split specimen. This revision is also consistent with the intent of the HHS Mandatory Guidelines.

Section 2.8(e) of Appendix A: Reduce the maximum number and percentage of blind performance test (BPT) specimens to be submitted per quarter but require a minimum

Revision: A revision to section 2.8(e) of Appendix A would reduce the maximum number and percentage of blind performance test (BPT) specimens that licensees submit to their HHS-certified laboratories from 50 percent to 20 percent for the initial 90-day period and from 10 percent to 3 percent after the initial period. This revision would be consistent with changes made to the HHS Mandatory Guidelines and the Department of Transportation's rules.

Purpose: As HHS did with its Mandatory Guidelines, the modifications would reduce the percentage of blind performance test specimens, reduce the proportion of blind performance tests relative to the total number of tests submitted, and reduce the maximum required number of blind performance test specimens. These changes are intended to ensure that the number of blind performance test specimens required to be submitted are adequate to assure quality in the testing process and particularly in the HHS-certified laboratory.

The maximum number of blind performance test specimens required to be submitted both in the initial 90-day period and after is also lowered in the proposed revision. However, the staff believes a maximum number less than that established by the HHS Mandatory Guidelines would assure adequate quality in the testing process. Whereas HHS lowered the maximum number of blind specimens to be submitted during the initial 90-day period from 500 samples to 200, the staff proposes a further reduction to 100 specimens. The maximum number of specimens submitted thereafter during each quarter was reduced from 250 to 100 by HHS; the staff proposes a further reduction to 25 blind specimens per quarter.

Because the FFD rule permits on-site testing and very few specimens with unconfirmed positive test results would be submitted to laboratories from sites performing on-site testing, the staff, in consultation with SAMHSA, proposes that there should be a minimum number of blind specimens (10 per quarter is proposed) to ensure that a sufficient number are submitted to assure the quality of the testing process.

Utilities with multiple collection sites submitting specimens to the same HHS-certified laboratory would be required to meet the percentage requirement for each collection site. However, a licensee may combine the number of specimens collected from its multiple sites to meet the total minimum requirement for all collection sites. That is, if one or more of the utility's collection sites and the corporate office contract with the same laboratory, they may pool their number of regular test specimens to meet requirements for the minimum number of blind performance test specimens. The rule would require that blind specimens would be submitted to the laboratories from each collection site and that submission would be uniformly distributed throughout each quarter to correspond with the submission rate for other specimens.

Licensee Cost Reduction/Increase: Estimated potential annual savings industry-wide are \$287,000.

Backfit Rule Considerations: This change is a relaxation in burden and the reduction is optional. Licensees continuing to meet the old requirements are virtually assured of meeting the new requirements, which are substantially reduced. The creation of a minimum number of BPT specimens (10) to be sent per quarter may increase the requirement in rare cases for licensees with on-site testing programs in instances where very few presumptive positive test results were sent for confirmation testing. The minimum is needed to assure that the BPT program is meaningful.

NEI proposed that the Commission entirely delete the blind performance test specimen requirements. In NEI's view, HHS-certified laboratories' ability to maintain their certification is sufficient proof of the quality of their testing service. The NRC staff disagrees with NEI's proposal. First, HHS itself does not view blind performance testing as duplicative of the HHS certification, and therefore the HHS Guidelines require blind performance specimen testing. HHS believes that blind performance specimen testing is useful for evaluating the effectiveness of the licensees' collection and shipping of specimens to the laboratories, to which HHS certification is not directed. Second, HHS and the NRC staff regard blind performance testing as an ongoing quality assurance measure for laboratory testing. Indeed, blind performance specimen testing was instrumental in identifying errors at HHS-certified laboratories. For example, in 1990,

there were 13 laboratory processing errors discovered through the use of blind performance specimens (see Appendix D to NUREG/CR-5778, Vol. 2). During the period January 1996 through July 1998, there were 25 laboratory processing errors discovered through the use of blind performance specimens (source: Individual reports to the NRC by licensees during that period). Therefore, NEI's proposed deletion of this important QA/QC measure is unacceptable.

This revision is consistent with the intent of the HHS Guidelines to reduce the maximum number and percentage of blind performance specimens to be submitted per quarter. Because several licensees conduct onsite testing and, therefore, submit a significantly lower number of specimens to the HHS-certified laboratory for further testing, the staff recommends that the NRC require a minimum of 30 samples during the initial 90-day period and 10 per quarter thereafter to provide a sufficient number of tests. The number of blind specimens is less than the number mandated by HHS (100/25 by NRC instead of 200/100 by HHS).

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement. This revision is also consistent with the intent of the HHS Mandatory Guidelines.

Section 2.9(e) of Appendix A: Minimum time for request by individual for reanalysis of original specimen added

Revision: A revision to section 2.9(e) of Appendix A would allow licensees to establish a time limit within which employees may request a reanalysis of their primary specimens.

Purpose: Section 2.9(e) currently allows employees to "timely" request MROs to retest their primary specimens after they are notified of a confirmed positive test result. Similar to the situation with section 2.7(k) discussed in Group IB above, this lack of clarity as to what qualifies as a "timely" request creates the potential for employees to request their primary specimens be retested several weeks or months after the first test results of their primary specimens were confirmed as positive. The proposed rule provided a minimum of 72 hours for a tested individual to request a retest, which was inconsistent with the HHS Guidelines. The basis for the proposed rule was to ensure that individuals be provided with sufficient time to request such testing, and that an explicit time period would minimize uncertainty with respect to the appropriate period for allowing such test requests.

Upon reconsideration of this matter, the NRC staff recommends that the Commission adopt a more flexible standard that will protect both the licensee's and employee's interests. The staff recommends that licensees be given the authority to establish

appropriate time limits for requesting retests consistent with the licensee's experience (e.g., notification of test result just before a long shift break, before a long holiday weekend, the individual out) but without specifying any specific time period. This would permit licensees to establish an appropriate period, but that there be a reasonable basis for the period. While an MRO may honor a request made beyond the licensee-established period, the MRO is not required to do so. The staff believes that providing such flexibility to the licensees outweighs any advantage from having a rule-prescribed period; the requirement that the period be "reasonably established" provides assurance that the licensee does not arbitrarily establish an inordinately-short period.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: Section 2.9(e) currently stipulates only that employees must make a "timely" request to have their primary specimens reanalyzed. This revision would clarify this current requirement by authorizing licensees to establish a "reasonable" limit on what is to be considered a "timely" request for reanalysis. It would also create consistency between, and thereby clarify, the two related section 2.7(k) and section 2.9(e) processes under which employees can request the testing of their split specimens and the retesting of their primary specimens. This revision is consistent with the intent of the HHS Guidelines that the retesting of specimens occur within a reasonable period after it is requested.

***Staff Conclusion:* This revision is not a backfit because it clarifies, but does not change, a current requirement concerning the meaning of "timely request" in section 2.9(e). NOTE: This revision was classified as a clarification because there is a current (but vague) requirement in section 2.9(e) that there be a "timely request." The revision to section 2.7(k) was classified as a worthwhile change because there was no timeliness standard. This revision is also consistent with the intent of the HHS Mandatory Guidelines.**

GROUP II: REDUCTION IN BURDEN

A. Changes with quantitative monetary benefits.

Section 26.2(f): Eliminate duplicate testing under multiple programs

Revision: A revision to section 26.2(f) would allow that people covered by a program regulated by another Federal agency or state need be covered by only those elements of a licensee's FFD program not included in the Federal agency or State program. This revision also sets forth certain standards that programs regulated by another Federal agency or State need to meet to be used as a substitute for a licensee's FFD program.

Purpose: This revision would reduce the burden on workers covered by multiple Federal and State programs with requirements that duplicate those of the NRC's rule.

Licensee Cost Reduction/Increase: There would be an estimated annual cost savings of \$207,200.

Backfit Rule Considerations: This revision would create a permissive relaxation of current requirements and, as such, would not fit within the definition of a backfit. Licensees are not required to change their programs. Licensees can continue to maintain the current multiple testing programs for certain individuals if they so choose.

The version of this revision published in the NRC's May 1996 Federal Register notice would have allowed acceptance of another Federal agency or State program as long as it "meets the general performance objectives" of Part 26. In its comments on that proposed revision, NEI recommended that the NRC clarify the meaning of "meets the general performance objectives." If that term were not clarified, NEI stated that varying interpretations could create the potential for noncompliance issues and accordingly a backfit justification should be prepared. In response to this and other public comments, the staff is now recommending in section 26.2(f) a more complete statement of the standards that programs regulated by another Federal agency or State must meet to be used as a substitute for a licensee's FFD program.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 26.20(f): Credit for unescorted access status granted by another licensee

Revision: This revision to section 26.20(f) would allow licensees to credit unescorted access status granted by other licensees. In such cases, the employees would have to be covered by the random testing and behavioral observation programs of either the original licensee employer or the host licensee.

Purpose: As currently written this section is unclear as to whether a licensee needs to audit another licensee's program before granting unescorted access to that licensee's employee. The proposed addition would eliminate that question as well as facilitate the interchange of employees in, for example, situations where a "peer evaluator" from one licensee works with another licensee.

Licensee Cost Reduction/Increase: The total estimated industry-wide annual savings is \$11,200.

Backfit Rule Considerations: This is an optional change for licensees. They can continue to maintain totally separate unescorted access status and drug testing for individuals employed by another licensee.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 26.21(b): Refresher training intervals extended from 1 to 2 years

Revision: Section 26.21(b) currently requires people assigned to activities within the scope of the FFD rule to receive refresher training on various FFD issues every 12 months. A revision to this section would decrease the frequency of refresher training from every 12 to every 24 months.

Purpose: NRC inspectors have found employees to be generally aware of FFD policies and the potential for FFD problems. In addition, the material presented in this training is relatively straight forward and is not expected to change significantly over time. A 24-month frequency should be sufficient.

Licensee Cost Reduction/Increase: Estimated potential industry-wide annual savings is \$6,832,000.

Backfit Rule Considerations: This is an optional change for licensees. They can continue to conduct annual refresher training.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

Section 26.21(b): Acceptance of generic portions of training provided by another licensee

Revision: This revision to section 26.21(b) would allow licensees to accept the generic portions of training of individuals who have been subject to another Part 26 program and who have had initial or refresher training by another licensee within the past 24 months, provided site specific training is completed.

Purpose: Policy communication and awareness training covers a number of common areas that are consistent across licensee programs. These include the personal and public health hazards associated with illegal drug use and legal drug abuse. It is not necessary for a worker to repeat the training in these generic issues at each site. Site specific training is still needed for all employees.

Licensee Cost Reduction/Increase: Estimated potential industry-wide annual savings are \$1,467,000.

Backfit Rule Considerations: This is an optional change for licensees. They can continue to require all individuals who received training at another site within the prescribed interval to take all portions of the drug awareness training at the new site.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

Section 26.22(c): Acceptance of generic portions of supervisory training provided by another licensee

Revision: A revision to section 26.22(c) would allow licensees to accept generic portions of supervisory FFD training from another licensee as long as site specific training was completed.

Purpose: This revision would facilitate the movement of supervisory personnel among licensees and decrease licensee costs for training supervisors in a number of areas that are common across licensee programs.

Licensee Cost Reduction/Increase: Estimated potential annual cost savings industry-wide would be \$258,000.

Backfit Rule Considerations: This is an optional change for licensees. They can continue to require all supervisors who received training at another site within the prescribed period to take all portions of the awareness training at the new site.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 26.24(a)(1): Flexibility in pre-access testing:

- ! *tests within past 60 days may be considered pre-access tests if they meet the standards of Part 26;*
- ! *access may be granted pending test results for individuals covered by an acceptable FFD program for 2 consecutive weeks in the past 6 months;*
- ! *no pre-access test for those transferring from another program who have been covered by an FFD program meeting the requirements of Part 26 for 30 of the past 60 days*

Revision: Section 26.24(a)(1) would be revised to allow any negative drug and alcohol test meeting Part 26 standards, and performed within 60 days before the granting of unescorted access, to serve as a pre-access test. Another proposed revision would allow licensees to grant unescorted access to employees before receipt of a negative pre-access test result when the employees have no history of substance abuse and either have had a negative test result in the past six months or have been covered by a program meeting Part 26 standards for a portion of that period.

Purpose: These revisions would eliminate unnecessarily redundant testing of applicants for unescorted access. They would also acknowledge the industry's experience of the demonstrated reliability of workers who have been covered by a rigorous program in the past. That experience indicates that workers who have been subject to an FFD program and have been found to be reliable should not have to wait for a negative test result before gaining access.

Licensee Cost Reduction/Increase: Estimated potential industry-wide annual savings would be \$784,000.

Backfit Rule Considerations: Each of these revisions would allow, but not mandate, licensees to make program changes that would tend to reduce regulatory burden. NEI indicated some resistance to these revisions, however. NEI stated that licensees would

have to track and manage new information about employees' work history to be able to take advantage of these relaxations of the pre-access testing requirement. While the staff believes that will not prove to be true, licensees need not take advantage of this permissive relaxation of requirements if they find doing so would be too complicated.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

Section 26.24(a)(2): Persons off site and unavailable when chosen for random testing may be tested when next on site

Revision: A revision to section 26.24(a)(2) would clarify the random testing requirement in cases where a person is chosen for random testing while away from the site. It would make it clear that the licensee need not immediately bring the person back to the site to be tested but instead can wait until the next time the person returns to the site to conduct the random test. The revision would also require that reasonable efforts be made to test persons selected for random testing. This revision is related to return-to-duty testing after prolonged absences (see section 26.24(a)(5) under Group IIA).

Purpose: This revision will serve two purposes. First, it will correct the current practice of some licensees that fail to test persons who are off site when chosen for random testing and, instead, choose someone else from the random testing pool to be tested. The staff has determined that, in many of these cases, licensees made little or no effort to test those persons and believes that the requirement to make a reasonable effort to test persons selected for random testing would properly convey the expectation without mandating actions that may not be realistic. This revision clarifies the existing requirement in section 26.24(a)(2) that people subject to random testing must have an equal probability of being randomly selected and tested. The current practice of some licensees to not test people who are off site when chosen for random testing runs counter to this requirement and decreases the randomness of the testing process by making the testing of some persons more probable than for others. Although predictable patterns of random testing are prohibited by the rule and random selection processes should permit no "safe periods," the staff concludes that reasonable efforts to test persons who are off site when selected for random testing will meet the intent of these requirements.

The second purpose of this revision is to provide flexibility to the approximately 40% of the licensees that currently call people chosen for random testing to the site from long distances to be tested rather than waiting to test them when they are next on site. This revision, in conjunction with the return-to-duty testing requirements in section 26.24(a)(5),

will make it clear to those licensees that they can adjust their testing programs to eliminate this unnecessarily expensive practice. The revision will enable these licensees to test these employees under the random program when they are next on site.

Licensee Cost Reduction/Increase: This revision would produce an estimated annual industry-wide savings of approximately \$670,000. These savings would accrue due to a reduction in travel time and costs for 40 percent of the licensees that currently call people in for testing rather than wait until they are reasonably available or brought back to the site for some other reason.

Backfit Rule Considerations: Section 26.24(a)(2) explicitly states that people subject to Part 26 requirements must have an equal probability of being randomly selected and actually tested when they are selected. The Commission has stressed that this means that people subject to Part 26 testing requirements have a continuous probability of being tested. (See, e.g., NUREG-1354, Item 7.5.8, p. 7-16.) Workers who are not tested because they are not on site when selected do not have an equal probability of being tested when compared to workers who are on site and tested.

The NRC has also stated that an acceptable random testing system cannot permit "safe periods" for any employee (NUREG-1385, Item 4.6, p.4); that item noted that people who are frequently off site must be as subject to random testing as those who work regular on-site shifts. Allowing people who are off site when randomly chosen to not be tested would, in effect, permit safe periods for these people and run counter to the NRC's intent. It should also be noted that this precise issue was addressed in the responses to public comments on the original proposed FFD rule. In response to a request that workers should be subject to random testing only while on duty, the NRC stated that the rule does not require that employees be called into work solely for purposes of testing (NUREG-1354, Item 7.5.6, p. 7-15). Instead, the NRC said that it expects that a worker will be tested at the first available opportunity once selected; licensees are expected to institute an approach to assure that absent workers are not omitted or tested at a lower rate than the program requires.

Despite these very clear directives, some licensees still inquire of the staff what constitutes a truly random testing process. Other licensees needlessly call people in from long distances when they are chosen for random testing. This revision would provide an explicit directive designed to eliminate both these problems.

NEI's comments on this issue expressed an approach to random testing that runs counter to these NRC directives. NEI contended that the fact that all people who are on site at

any particular time are subject to random testing assures a system that is statistically random. Further, if someone who is selected to be tested is not on site, another person on the randomly chosen list of people to be tested can be tested instead. NEI's contentions are incorrect, for the reasons discussed above.

NEI recommended deletion of this "testing-upon-return" requirement, arguing that it would pose a cumbersome and unnecessary administrative burden to keep track of the testing required when people return to the site. The staff disagrees with NEI's contentions. Several licensees agreed with this revision and noted that their practices already conformed to the revised requirements and that they have experienced no administrative burden. Some commenters apparently assumed that this revision would require that FFD staff have a constant presence on site so that employees would be tested no matter when they returned. The rule language has been amended to require that such tests be conducted at the earliest reasonable and practical opportunity.

Staff Conclusion: This revision: a) fits within the Backfit Rule's compliance exception for those licensees that fail to test people who are off site when selected and b) is a permissive relaxation of a current requirement for those licensees calling people who are offsite to be tested.

Section 26.24(a)(3): People tested for cause for alcohol can return to duty while awaiting urinalysis results

Revision: Section 26.24(a)(3) would be revised to allow people who are tested for cause for suspected use of alcohol, have had a negative alcohol test, and have been determined to be fit for duty by a medical and management determination of fitness to be returned to duty pending the results of the urinalysis test.

Purpose: This revision would recognize that there is no good reason to keep an employee away from work in these circumstances. The employee's fitness to perform his or her duties will be confirmed and there will be very little reason to expect the employee had been abusing drugs. The NRC recognizes that polysubstance abuse involving alcohol and one or more proscribed drugs does occur, however, the employee's fitness will be confirmed.

Licensee Cost Reduction/Increase: The estimated potential industry-wide annual savings would be \$148,000.

Backfit Rule Considerations: This relaxation of current requirements will allow licensees to send employees who are judged fit back to work before obtaining drug test results if they choose to do so. They can continue to maintain current requirements if that seems more appropriate.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

Commission Determination: The Commission has decided not to adopt the staff's recommendation with respect to a medical determination of fitness pending the results of a urinalysis test after a negative alcohol test, consistent with the Commission's determination (see pp. 125-126 on §26.24(a)(3)) that a medical determination of fitness is not necessary following a negative for-cause test.

Section 26.24(a)(5): Clarify existing testing requirements for persons unavailable for testing for short periods and insure consistency with the access authorization program

Revision: A new section 26.24(a)(5) would add a fifth type of required chemical testing referred to as "return-to-duty" testing. It would require that personnel with unescorted access are tested when they return from extended absences (60 days or more) and when seeking to regain unescorted access after violating the licensee's FFD program. The third part of the revision would allow immediate access of those being return-to-duty tested if they have no history of substance abuse and have either had a negative test result during the past six months or been covered by an FFD program for two consecutive weeks over that period. The first part of this revision concerning tests after extended absences is related to the random testing of persons who are off site when selected [see section 26.24(a)(2) under Group IIA].

Purpose: The first part of the proposed change would require licensees to test personnel who seek to regain access to the protected area after an absence from the possibility of being tested under the particular licensee's FFD program for more than 60 days, or after being removed for cause. The 60-day period was chosen in order to be consistent with the current pre-access limitations in NUMARC 91-03, "Nuclear Power Plant Personnel Access Authorization Data Exchange Guidelines," dated October 1992. The industry guidelines provide that, to be issued a badge in a situation where an individual has an existing access authorization, the individual must either be currently covered by an FFD program including random testing, or have satisfactorily completed pre-access drug and alcohol testing within 60 days prior to badging, and be subject to a behavioral observation program and FFD program.

The second part of the proposed revision would make it clear that workers seeking to regain access after having been denied access be required to take a return-to-duty test and obtain a negative test result before being granted access. In its current form, Section 26.27(b) of the rule does not clearly state the Commission's intent that licensees should test personnel having unescorted access when they return to work after violating the licensee's FFD program as part of the medical assurance of fitness. There is some evidence that NRC licensees are not retesting individuals before returning those individuals to duty after a FFD violation. For example, in 1992, a licensed operator at Indian Point Unit 3 tested positive for marijuana, and was returned to duty after 14 days without a test. After returning to duty, the operator was retested (in response to an NRC request for information) and the operator tested positive on the second test. The staff believes that there is a finite possibility of individuals continuing to violate FFD policies after detection and removal from duty. For example, data reported by licensees indicates that there were 408 positive followup tests. These are workers who were given a "second chance" and failed to abstain from substance abuse. This is not meant to discredit the many workers who have modified their behavior and are now effective workers. The Department of Transportation reports that return-to-service testing during a one-year period produced a positive test rate of 2.8 percent. These were people who knew they would be tested and that, if they tested positive, they would not get their jobs back. Thus, the staff believes that return-to-duty testing would provide an additional worthwhile improvement by detecting continuing substance abuse. This revision would be consistent with prevailing industry practice. The staff is aware that most, but not all, licensees have already instituted return-to-duty testing of people seeking to regain access after an FFD policy violation as the Commission originally intended as part of the medical determination of fitness required by sections 26.27(b)(2) and (4).

The third part of the proposed change would allow immediate access for employees who have taken a return-to-duty test if they have no history of substance abuse and have either a negative test result during the past six months or have been covered by an FFD program during two consecutive weeks over the past six months.

Licensee Cost Reduction/Increase: The staff is aware that most, but not all, licensees have already instituted return-to-duty testing of people seeking to regain access after an FFD policy violation as part of the medical assurance of fitness required by section 26.27(b)(2) and (4). Therefore, there would be no costs associated with this revision.

Insofar as the testing of those returning after extended absences is concerned, this revision is designed to eliminate some current testing that is not necessary to achieve the rule's current requirements for pre-access testing in section 26.24(a)(1) and random

testing in section 26.24(a)(2). This revision would, for example, relieve the testing requirements for a person who, having obtained a negative drug and alcohol test at one licensee during the past two months, is seeking to regain access at another licensee. In that case, the current section 26.24(a)(1) requires a pre-access test. However, if the person has retained a "current" access status they may have been selected for random testing but were not readily available. The staff estimates that each facility is administering approximately 175 return-to-duty tests of people each year who are on site infrequently and as an alternative to random testing. It is assumed that this revision would allow licensees to eliminate the testing of 25 percent of these people. This would produce an estimated industry-wide annual savings of \$493,000 above that estimated from changes to section 26.24(a)(1) and (2).

With respect to the third part of this revision (allow immediate access when specified conditions are met), the staff estimates that 66 employees per year at each facility would be granted immediate access under this rule provision. This would result in annual industry-wide savings of approximately \$1,322,000. The total savings of \$1,815,000 discussed here is over and above the \$670,000 savings ascribed to this proposed revision in conjunction with the related proposed revision to section 26.24(a)(2) as discussed above.

Backfit Rule Considerations: With respect to the first part of this revision, the application of the FFD program to persons absent from the possibility of being tested during extended absences, the change would assure the fitness of a person who has not been realistically covered by the FFD rule for an extended period. In that case, there is probably no behavioral observation and little or no possibility of being randomly tested; the detection and deterrent features of the FFD rule are not being applied. Therefore, this part of the revision is important for the protection of public health and safety.

With respect to the second part of this revision, the Commission explicitly stated in the current section 26.27(b)(2) and (4) that there must be a satisfactory medical assurance of fitness before an individual can be returned to duty after a positive drug test. Although the rule did not explicitly require a drug test, item 12.6.3 in NUREG-1354 stated that the NRC expects that such testing would be the normal practice for those being returned to duty. Unfortunately, there is still a compliance problem associated with this requirement in that some licensees do not test people before returning them to duty. While the addition of this section would create a new category of testing, it would not create new testing requirements. Instead, it would clarify existing requirements and practices to ensure that the licensees that are not testing people in these circumstances do so. It would also reduce expensive and unnecessary over-compliance by some utilities.

With respect to the third part of this revision, allowance of immediate access when certain conditions are met, licensees will still have the option of waiting for the test result before granting unescorted access. The staff believes that permitting immediate access where there is no history of substance abuse and previous coverage by an FFD program would not jeopardize public health and safety and would provide some reduction in burden.

Staff Conclusion: The first part of this revision concerning tests after extended absences is a worthwhile change that the staff recommends be adopted as an exception to the Backfit Rule because it assures the fitness of a person who has not been realistically covered by the FFD rule for an extended period and, therefore, is important to the protection of public health and safety. The second part of this revision concerning testing before return to duty after removal fits within the Backfit Rule's compliance exception. The third part of this revision concerning allowance of immediate access when certain conditions are met is not a backfit because it is a permissive relaxation of a current requirement.

Section 26.24(e): Limit the time between notification and specimen collection

Revision: A new section 26.24(e) would require that licensees keep to a minimum, consistent with operational constraints, the time between notifying individuals to be tested and the actual collection of specimens.

Purpose: Section 2.4(g) of Appendix A currently requires licensees to prevent dilution and adulteration and to assure that authentic specimens are collected. This proposed new section 26.24(e) is intended to assure compliance with section 2.4(g) by eliminating a significant vulnerability (time) in the specimen collection process. Time is very important to persons attempting to avoid detection. Time enables them to flush themselves, obtain surrogate specimens, or obtain materials to dilute or adulterate their specimens. For example, an investigation was conducted to determine why two adjacent sites, drawing their workforce from the same geographic area, had significantly different positive rates for random tests. It was determined that different time intervals between notification and collection was the cause of the discrepancy. The licensee with the low rate had a 2-hour notification policy not vigorously enforced; the licensee with the higher rate had a 15-minute notification policy which it aggressively enforced. A DOT study showed an increase in the positive rate when there was little or no prior warning of specimen collection. Whereas "normal" random testing of motor carrier personnel was positive at a 2.5 percent rate, roadside stops produced a 4.8 percent positive rate. In response to that experience, DOT revised its rule to require the person, upon notification, to immediately

proceed to be tested. NRC inspections and surveys indicate that some licensees keep workers on the job and test them only at the end of a shift even though they have been notified that they are to be tested hours before. In other cases, licensees permit delaying tactics that result in lengthy periods between notification and testing. In both of these cases, alcohol can be metabolized below detectable levels and the person can flush himself or herself, to some degree, of drugs. Some licensees release workers for tests in a manner that allows them ample opportunity to obtain materials that might subvert the test results (e.g., adulterants or surrogate samples kept in a locker or vehicle). The NRC understands that operational necessity may prevent the tested person from reporting immediately and that being escorted between notification and test may be an unreasonable burden. However, several licensees have reduced the notification time by using the supervisor to coordinate the worker's availability for testing and withhold notification until the individual must proceed to the collection site. Licensees report that this approach does not cause any burden or inconvenience; it is merely a different way of doing things. One licensee reported that it escorted persons selected for random testing without giving them prior notice, which produced a low number of questionable specimens (NUREG/CR-5758, "Fitness for Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports," CY 1994, Volume 5, page C-5). Therefore, the Commission expects that licensees will assure that opportunities for subverting the test are eliminated as much as is practicable.

Licensee Cost Reduction/Increase: Licensees currently minimizing time between notification and specimen collection report that it does not cost more, it is just a different way of doing things. Licensees not currently in compliance may experience a reduced number of tests that have to be repeated and dilute specimens that have to be specially processed; licensees who have implemented these measures have reported a dramatic decrease in the number of questionable specimens. This will create an estimated annual industry-wide savings of \$118,400.

Backfit Rule Considerations: Section 2.4(g) of Appendix A explicitly requires licensees to take measures to prevent adulteration and dilution of specimens and assure specimens collected are authentic. Minimizing the time between testing notification and specimen collection is a basic measure to prevent subversion of the testing process that some licensees are failing to take. The revision would rectify this situation by clearly requiring all licensees to minimize this time interval. By doing so, it would provide an increase in safety by reducing the possibility of subversion of the testing process, and would do so along with a reduced burden.

Staff Conclusion: This revision fits within the Backfit Rule's compliance exception.

Section 26.27(a): Fitness history need not be obtained for those covered by other programs or who are absent for 30 days or less

Revision: This revision to section 26.27(a) would have stipulated that a suitable inquiry need not be conducted for any period of 30 days or less that the applicant for unescorted access was not covered by an FFD program meeting Part 26 requirements.

Purpose: Section 26.27(a)(2) currently requires the licensee to complete a suitable inquiry, which is currently defined in section 26.3 as a verification of employment history for the past five years. This revision would have permitted licensees to not conduct a suitable inquiry for any period of 30 days or less that the applicant for unescorted access was not covered by an FFD program, which would have included instances of employment of less than 30 days outside the nuclear power industry. After the proposed rule was published, the staff was informed that derogatory information is frequently obtained through checks of employment of less than 30 days; in these cases, the individual was terminated for cause, frequently for substance abuse. Since it appears that the proposed revision would increase the risk to public health and safety, this proposed revision to section 26.27(a)(4) has been withdrawn.

Licensee Cost Reduction/Increase: None

Backfit Rule Considerations: NEI asserted that this change and two other changes to this section which are discussed in Group IIB and Group IIIB, should be backfits unless further relaxations were provided (e.g., NEI wanted to grant unescorted access with essentially no effort to determine the person's substance abuse history). The NRC staff has never accepted NEI's approach for granting unescorted access. Since the staff has received information after the proposed rule was published that would lead the staff to conclude that the proposed revision would increase the risk to public health and safety, the revision has been withdrawn.

Staff Conclusion: Not applicable

Section 26.71(d): Reduce frequency of program performance reports

Revision: A revision to section 26.71(d) would allow licensees to submit program performance reports once a year instead of once every six months.

Purpose: The current section 26.7(d) requires licensees to submit program performance reports every 6 months. The current reporting requirements were considered necessary for the staff to facilitate its oversight of the initial implementation of the rule but are no longer required. Yearly reports will enable staff to meet the Commission's tasking to assure that adequate data are collected so that licensee programs can be analyzed, and the effectiveness assessed, so that appropriate improvements or changes can be made to the FFD rule (Item #7 of SRM dated March 22, 1989.)

Licensee Cost Reduction/Increase: Estimated potential industry-wide annual cost savings are \$148,000.

Backfit Rule Considerations: Section 26.71(d) would be revised to allow licensees to submit program performance reports once a year instead of every 6 months. This is a permissive relaxation of requirements since licensees can continue to prepare reports every six months.

NEI asked the NRC to change the FFD program performance data reporting requirement from "each site" to "each utility." In NEI's view, the rule's current requirement creates an unnecessary burden on those licensees. No backfit issues is raised by NEI's comment. Rather, it is a substantive comment recommending the aggregation of data currently required to be reported separately to the NRC. As the Commission stated in its Notice of Proposed Rulemaking (61 FR 21118; May 9, 1996), it considered, but decided not to adopt, a recommendation that utilities with more an one site submit only a single semi-annual program performance report for all sites. The Commission rejected that recommendation because of its need to be able to analyze program performance on a site-by-site basis. Since the NRC is not proposing to change this current reporting requirement, the staff concludes that no backfit issue was raised by the NEI comment, and that the NEI recommendation should be rejected.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 26.80(a): Change to performance-based audit as the basis for reducing required frequency

Revision: A revision to section 26.80(a) would allow licensees to conduct audits of certain FFD program elements as needed but no less frequently than every three years instead of conducting complete audits annually.

Purpose: This revision responds to a petition for rulemaking (PRM-26-1) and would promote performance-based rather than compliance-based audit activities. The audit program would be conducted so that all program elements are adequately covered at least once during the 3-year period and as indicated by analysis of program performance indicators. The proposed rule change further clarifies that programs must be audited following a significant change in personnel, procedures, or equipment as soon as reasonably practicable but no later than 12 months after the changes. The NRC recognizes that FFD is an evolving discipline and new issues and problems will continue to arise. In some cases, turnover of FFD program personnel and turnover in contracted services, such as specimen collections, MRO reviews, and EAP services further exacerbates the problems. Licensee audits have found many problems that were associated in some way with personnel changes and the new personnel not understanding their jobs or the implications of things they did, did not do, or changed. The purpose of these focused audits would be to assure that the change has not adversely affected the operation of the particular program element or function in question.

Licensee Cost Reduction/Increase: Although licensees would be able to reduce annual costs by about \$600,000 by reducing audit frequency under this revision, they would also be required to create and analyze program performance measures, an added cost estimated to be approximately \$81,000 per year (\$1,100 per licensee). The regulatory analysis estimates that the overall potential annual net industry-wide savings would be approximately \$518,000.

Backfit Rule Considerations: This revision would permit licensees to modify their current audit programs to adopt more performance-based and proactive approaches. In doing so, the staff expects that licensees could reduce their costs for performing audits. It is anticipated, however, that licensees' current practice of conducting complete annual audits of their entire FFD programs would continue to meet section 26.80(a) audit requirements as revised. This revision would, therefore, be a permissive relaxation in requirements.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

NEW: Section 26.80(a): Stipulate that licensees must continue to audit HHS-certified laboratories.

Revision: This revision would clarify that licensees must continue to audit their HHS-certified laboratories annually.

Purpose: This revision would state explicitly the need for continuing annual audits of HHS-certified laboratories. Section 26.80(a) requires licensees to audit their FFD programs, including "those portions...implemented by contractors and vendors" on an annual basis. Section 26.80(c) of the rule states that "NRC Guidelines require licensee audits of HHS-certified laboratories as described in Appendix A", and the current section 2.7(m) of Appendix A discusses inspections of HHS-certified laboratories but does not specify a specific frequency for conducting the audits. A May 1994 NRC OGC memorandum advised the staff that the rule, as currently written, does not explicitly require licensees to *annually* audit their HHS-certified laboratories and therefore the current language was not sufficient to support enforcement action. OGC has subsequently advised the staff that a HHS-certified laboratory is a "contractor" or "vendor" that implements part of the licensees' FFD program, and therefore is subject to the annual audit requirement of section 26.80(a). Nonetheless, because at least one licensee has not conducted such audits on the basis that the rule does not explicitly refer to HHS - certified laboratories, the Staff concludes that the rule should be appropriately clarified to make explicit the need for annual audits.

Licensee Cost Reduction/Increase: Most licensees are currently auditing their HHS-certified laboratories annually, and therefore this revision would create no new cost impacts.

Backfit Rule Considerations: Section 26.80 of the current rule explicitly requires licensees to conduct annual audits of the portions of FFD programs implemented by contractors and vendors. HHS-certified laboratories and any other contracted program support, such as collection and MRO services, and on-site testing are "contractors" and/or "vendors" and thus are covered by the current rule. When it published the original FFD rule in 1989, the NRC made reference to the need to ensure the proper qualifications of people who audit testing laboratories, i.e., knowledgeable about the forensic implication of laboratory procedures, and because the requisite skills are likely to be rare licensees will probably find it necessary to contract for such staff (54 FR 24487, June 7, 1989). In NUREG-1385,

the Commission also made explicit reference to the characteristics it expected of licensee audits of HHS-certified laboratories (Questions 11.3-1.5 of NUREG-1385, October 1989; p. 14). Thus, this proposed revision to section 26.80(a) clarifies the existing requirement and does not represent a changed position.

NEI argued that this audit requirement should be justified as a backfit because it would create a new burden on licensees. NEI cited the May 1994 NRC OGC memorandum to support its position. NEI characterized the memo as stating that the rule, as currently written, does not require licensees to annually audit their HHS-certified laboratories. NEI objected to what it considered a new requirement because, in NEI's view, it needlessly duplicates HHS's ongoing biannual audit/inspections of the laboratories it certifies. OGC has since advised the Staff that since HHS-certified laboratories are a vendor or contractor implementing a portion of a licensee's FFD program, such laboratories must be audited annually by the licensee under a plain reading of the current rule. Furthermore, OGC has taken the position that the proposed revision does not constitute a general backfit since an internal OGC memorandum whose position was not generally conveyed to the industry does not constitute a changed NRC position for purposes of the Backfit Rule, although there may be a compliance backfit with respect to those licensees who were advised by the NRC of the 1994 OGC memorandum.

With respect to duplication of HHS's inspections, the proposed revision to Section 2.7(n) of Appendix A published in the Federal Register on May 9, 1996, stated that annual licensee audits of the HHS-certified laboratories need not duplicate areas covered by the HHS inspection. When the Commission considered public comments during the development of the current rule, it considered several alternatives to the use of HHS-certified laboratories. See 54 FR 24482, 24483, June 7, 1989. The Commission concluded that the rigor of the HHS-certification program was not matched by the alternatives, and that the highest standards are needed to assure that the testing process is accurate, produces valid results, and provides suitable protection for those being tested. During implementation of the rule several unsatisfactory testing results have been identified by licensees. Many of these were caused by inadequate laboratory procedures (see Appendix D to NUREG-5758, Volume 2, which reported 8 unsatisfactory testing results on personnel specimens in 1990 and 1991 and 81 unsatisfactory results on blind performance specimens that were attributed to the laboratory during the same period). During the period January 1996 through July 1998, there were no reported problems with personnel specimens, although there were 25 laboratory processing errors discovered through the use of blind performance specimens. The primary causes for these unsatisfactory testing results were procedural errors outside the scope of the HHS-certification inspection. In addition, licensee audits continue to discover problems in

areas subject to HHS inspections such as cut-off levels, confirmation testing and sample handling. In one case, for example, the licensee's auditors had found sufficient problems to require a stop-work order. The laboratory subsequently lost its HHS certification. Therefore, the staff continues to believe that licensee audits of HHS-certified laboratories are an important element of effective FFD programs which are expected to produce consistent, valid results. The staff also notes that it has been informed by senior management at several HHS-certified laboratories that they appreciate the professionalism of licensees' auditors, the quality of their work, and the opportunity to discuss and resolve findings with them. They all indicated that the Part 26 mandated auditing process had improved their laboratories' performance. Accordingly, the staff does not support NEI's request that the rule be changed to no longer require licensees to annually audit HHS-certified laboratories.

Staff Conclusion: This revision is a clarification of an existing requirement and does not represent a changed position constituting a backfit. Alternatively, it could be viewed as a compliance backfit.

Section 2.2(a) of Appendix A: Permit prompt destruction of chain-of-custody forms showing negative test results

Revision: A revised section 2.2(a) of Appendix A would explicitly allow licensees to discard chain-of-custody forms showing negative results.

Purpose: This revision would allow licensees to discard chain-of-custody forms associated with negative tests since their retention serves no useful purpose.

Licensee Cost Reduction/Increase: The estimated annual industry-wide cost reduction is \$851,000.

Backfit Rule Considerations: This is a permissive relaxation of requirements. Licensees can continue to record and store chain-of-custody forms from negative test results.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

Section 2.3(2) of Appendix A: Extend reinvestigation interval for FFD program personnel from 3 to 5 years

Revision: Revisions to section 2.3(2), [section 2.3(c) in the revised rule] of Appendix A for the most part, would simply make editorial changes to the current wording. The only substantive revision would be to reduce the required frequency of the subsequent background checks from once every three years to once every five years.

Purpose: Section 2.3 of Appendix A currently requires that licensees carefully select and monitor "persons responsible for administering the testing program" based upon the highest standards of honesty and integrity. Section 2.3(2) currently requires licensees to conduct background checks and psychological evaluations of people they hire for these positions and to do follow-up evaluations once every three years thereafter. The proposed reduction in required frequency of subsequent background checks and psychological evaluations from once every three years to once every five years would not reduce the honesty and integrity standards to any appreciable degree.

Licensee Cost Reduction/Increase: The estimated annual potential industry-wide savings is \$7,000.

Backfit Rule Considerations: This revision is a relaxation of requirements. Licensees can, at their option, continue to conduct background investigations for FFD personnel every three years or reduce the frequency to once every five years. NEI recommended that the reinvestigation requirement apply only to FFD program personnel who are not covered by an approved behavioral observation program, which requires individuals to report to the licensee all applicable arrests. The Staff does not believe that the NEI alternative is acceptable. The Staff is aware that licensees have had problems with individuals reporting arrests (which is not an unexpected behavior), and that licensee management have on occasion inordinately delayed taking action on behavioral observations, or have not taken any action. Accordingly the staff concludes that NEI's recommended approach would not meet the current requirement that FFD program personnel meet the highest standards of honesty and integrity.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 2.4(g)(18) of Appendix A: Eliminate second breath specimen when test shows no alcohol

Revision: Section 2.4(g)(18) of Appendix A would be revised to eliminate the requirement for a second breath specimen unless the first specimen is not essentially zero.

Purpose: The second breath specimen serves no purpose if the first specimen is essentially zero. Having to give a second breath specimen in all cases for the initial screening tests, as currently required after a 2-10 minute wait, increases the time an individual must be away from his or her job unnecessarily.

Licensee Cost Reduction/Increase: The estimated potential annual cost savings from this revision, industry-wide, is \$1,165,000.

Backfit Rule Considerations: Licensees can continue to have their employees provide a second breath specimen for the screening tests when the first specimen is negative if they so choose.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

*Section 2.7(e) of Appendix A: **Conduct special processing of questionable specimens at HHS-certified laboratory (formerly: Test questionable specimens to limit of detection)***

Revision: A proposed new section 2.7(e) of Appendix A would require the testing of all specimens to determine their validity and the special processing of those specimens found to be of questionable validity. The part of section 2.7(e) discussed here pertains to the special processing of specimens of questionable validity at HHS-certified laboratories. This proposed revision would include the newly proposed requirement that HHS-certified laboratories conduct screening tests of specimens of questionable validity by comparing the responses of donor specimens to the negative screening control response. Those specimens that have responses that are greater than the negative control response would be subject to confirmation testing by GC/MS at the HHS-certified laboratory's limit of detection (LOD). Experience indicates that the vast majority of the specimens will be valid, and that some will be clearly invalid. The small number of questionable specimens that remain (due to probable dilution) would be tested at the LOD.

A related part of the proposed new section 2.7(e) would require HHS-certified laboratories to conduct validity testing on all specimens they receive from licensees. This proposed revision is discussed in Group IB. The remaining part of the new section 2.7(e), which would require licensees that conduct on-site testing to test for specimen validity at their testing facilities, is discussed in Group IIIA.

Purpose: The current section 2.7(d) of Appendix A permits, but does not require, "special processing" (meaning testing to limit of detection) of specimens suspected of being adulterated or diluted. The current section 2.7(i) indirectly requires LOD testing by stating that the retesting of primary specimens "...is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite." Many licensees have availed themselves of the permissive language to make noteworthy improvements in their FFD programs. The new section 2.7(e) would require licensees to conduct the special processing under a uniform set of procedures and criteria. Recognizing the ability of HHS-certified laboratories to identify drug metabolites at lower concentration levels found in dilute specimens in a forensically sound manner, the staff believes that LOD testing is an appropriate approach to assuring correct conclusions from those specimens found to be of questionable validity. The LOD would be used because, according to HHS's Addiction Research Center, the concentration levels of drugs or metabolites are frequently reduced up to 10 times from dilution; using normal cut-off levels would produce false negative results.

This revision would increase licensees' ability to detect evidence of adulteration or dilution, thereby reducing the potential for subversion of the testing process. Testing of specimens that have been found to be of questionable validity in the manner contemplated by this revision would be the best way to ensure that specimens that have been adulterated or diluted are detected and result in violations of the licensee's program policy. The laboratory testing conducted in accordance with this revision would help the MRO determine whether or not the dilution had an acceptable explanation or whether the specimen donor was trying to subvert the testing process.

Licensee Cost Reduction/Increase: The staff estimates that up to 2 percent of all specimens may require special processing because they have been determined to have questionable validity. (Note: A specimen determined to be invalid because it was adulterated, diluted, or a surrogate specimen is no longer of questionable validity - the staff estimates that 4 percent of all specimens will be invalid.) The staff is aware that, although the costs for confirmatory testing vary across the industry, a majority of licensees are obtaining LOD confirmatory testing as part of their laboratory services free of extra charge. For those licensees that are not currently obtaining such services without

additional charge, this revision may slightly increase the costs of testing specimens of questionable validity. It should be noted that such minimal cost increases would be at least partially offset by savings derived from eliminating some second observed collections and tests. The processing of suspect specimens at detection levels lower than those under which normal specimens are tested will enable MROs to make judgments about whether many of these questionable specimens were diluted deliberately because of the existence of drugs. This will reduced the need to collect second observed specimens and will save licensees the collection and testing costs associated with these specimens. In summary, although some licensees may face slightly increased costs, those costs would likely be offset by industry-wide savings from the costs of recollecting specimens under direct observation, testing, etc.

Backfit Rule Considerations: The Commission has indicated in the current rule that special processing (testing to LOD) is acceptable in certain situations. Section 2.7(e) would require licensees to conduct the special processing under a uniform set of procedures and criteria. This revision is an important component of specimen validity testing because the results will enable MROs to determine, in many cases, whether dilution was an attempt to subvert the testing process, or whether another specimen needs to be collected. In summary, this revision will provide some industry-wide savings and significant benefits, primarily improved protection of public health and safety through reduced subversion of the testing process and enhanced ability to identify substance abusers in the workplace.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule. The revision would enable MROs to determine, in many cases, whether dilution was an attempt to subvert the testing process, or whether another specimen needs to be collected. The revision would provide an improved capability of detecting substance abusers who are attempting to subvert the testing process. The costs of the testing would be offset somewhat by the need for fewer specimen recollections.**

Section 2.7(h)(2) of Appendix A: Permit MRO staff to perform certain support functions

Revision: A revision to section 2.7(h)(2) of Appendix A would permit MRO staff to perform routine administrative support functions, including receipt of test results and scheduling interviews for the MRO. The current rule restricts these activities to the MRO.

Purpose: There is no good reason why MROs have to perform these routine tasks. This revision would, therefore, increase efficiency and reduce costs.

Licensee Cost Reduction/Increase: The total estimated potential industry-wide annual savings would be \$44,400.

Backfit Rule Considerations: This is a permissive relaxation of requirements. Licensees can continue to require that MROs perform these duties if they so choose.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 2.7(n) of Appendix A: Eliminate need to audit areas covered by HHS inspections

Revision: This revision to section 2.7(n) [section 2.7(m) in the current rule] of Appendix A would permit licensees to forgo auditing specific programmatic areas of HHS-certified laboratories which were audited in HHS certification inspections. To determine what areas were audited in an HHS certification inspection, the revision would require that licensees' inspections and audits of HHS-certified laboratories include a review of reports made under the HHS certification program to determine the areas covered by the HHS inspection. A related change to section 2.7(n) concerning licensee and NRC access to HHS certification inspection reports is described under Group IIIB.

Purpose: The current section 2.7(m) of Appendix A (along with the current section 26.80) require licensees to conduct an audit of HHS - certified laboratories to ensure that those portions of the licensee's FFD program are effective. The staff has determined that there is no need to require licensees to duplicate areas covered by the HHS certification inspection. A licensee who wishes to avoid inspecting areas covered by an HHS certification inspection would need to review HHS reports to determine what section of its audit has been audited by HHS.

Licensee Cost Reduction/Increase: This revision would create an estimated annual industry-wide savings of approximately \$40,000 by eliminating some currently redundant audit activities.

Backfit Rule Considerations: This is a permissive relaxation of requirements. Licensees can continue to do a full audit of HHS-certified laboratories if they so choose.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

B. Changes that provide greater flexibility and indeterminate monetary benefits.

Section 26.2(e): Clarify requirements during decommissioning

Revision: A new section 26.2(e) would have been created to clarify that licensees who are decommissioning their nuclear power plant must continue to maintain FFD programs after the certification under Section 50.82(a)(1), unless the NRC has approved a reduced scope FFD program to persons and specified areas deemed appropriate by the NRC to protect public health and safety.

Purpose: This revision would have corrected an error in the 1996 Decommissioning Rule (61 FR 39301; July 29, 1996) to require licensees who have made the certification under Section 50.82(a)(1) to continue to implement their FFD program unless the licensee has requested and obtained NRC approval to reduce the scope of FFD program.

Licensee Cost Reduction/Increase: The proposed revision would have imposed costs on some current licensees who are decommissioning their reactor and have completely discontinued their FFD programs because of the Commission's 1996 decommissioning rule, which failed to make a conforming change to Part 26 thereby erroneously permitting licensees who certified under Section 50.82(a)(2) to completely discontinue their FFD programs.

Backfit Rule Considerations: Section 26.2(a) of the current rule requires all licensees *authorized to operate* a nuclear power reactor to implement an FFD program. Until the 1996 revisions to 10 CFR 50.82, licensees in the process of decommissioning still held a Part 50 license which authorized them to operate; accordingly, such licensees were required to maintain an FFD program. When 10 CFR 50.82 was adopted, which removed the authority to operate once the licensee certified that it had permanently removed fuel from the reactor vessel and had permanently ceased operations, a conforming amendment to Section 26.2 was not made to require the licensee to continue the FFD program at the decommissioning plant.

Upon reconsideration, the Staff believes that the issue of FFD applicability to decommissioning plant should not be resolved in this FFD rulemaking. Rather, the issue of FFD applicability should be resolved as part of an integrated staff reassessment of the technical and regulatory bases for applicability of the Commission's regulations for operating nuclear power plants (e.g., Maintenance Rule, 10 CFR 50.64, emergency

preparedness, 10 CFR 50.47 and 50.54(q)) to decommissioning plants. Therefore, the Staff has withdrawn this proposed revision.

Staff Conclusion: Not applicable.

Section 26.22(c): Refresher training intervals may be extended from 12 to 36 months if written exam is given every 12 months

Revision: A revision to section 26.22(c) would allow licensees the flexibility to use a written examination on pertinent FFD issues in lieu of refresher training of supervisors and escorts in two out of every three years.

Purpose: Section 26.22(a) and (b) currently require that supervisors of licensee employees and contractor personnel and all escorts understand their responsibilities in implementing the FFD program. In order to assure that this knowledge and awareness is maintained, the current section 26.22(c) requires annual training of such supervisory personnel. Supervisory FFD training ensures that supervisors and escorts will be able to successfully fulfill their key role in implementing FFD programs. Supervisors and escorts must, for example, be continuously able to recognize drug use or degradation of performance of the people working around them. To remain effective they must be made aware of the most current techniques for effectively performing these functions. A written exam that demonstrates an adequate knowledge of pertinent FFD issues and material to be used in lieu of refresher training for supervisors and escorts in two out of every three years should decrease licensee administrative expenses without compromising the effectiveness of FFD programs. However, refresher training will still be mandatory at least once every 36 months.

Licensee Cost Reduction/Increase: Some indeterminate savings may be realized.

Backfit Rule Considerations: This proposed revision would reduce licensee burden by allowing a written examination to be used for supervisors in two out of three years instead of the more costly classroom refresher training which is currently required.

NEI objected to any classroom training and recommended a "test-out" type of examination to satisfy all refresher training requirements. The staff believes that a classroom-type training session is needed and that a three year interval between classroom sessions is as much relaxation that would be prudent, as long as other actions such as exams are used to refresh and demonstrate the required knowledge during the intervening period.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

Section 26.24(a)(3): Provide flexibility in timeliness of for-cause test

Revision: A revision to section 26.24(a)(3) would provide flexibility to conduct for-cause tests as soon as practicable, but no more than 2 hours for the alcohol part of the test and 8 hours for the drug part of the test following an indicated need for testing.

Other revisions to this section (discussed under Group IIIB, below) would be a clarification of the conditions that initiate a for-cause test and clarification that an MRO or other licensed medical person must determine the fitness for duty of an individual tested for cause before that worker may return to duty.

Purpose: The current rule at section 26.24(a)(3) requires that specimens be collected for "for-cause" testing "as soon as possible" following several described conditions. While it is usually desirable to collect the specimens as soon as possible (the only exception being after substance abuse is observed, a few hours may be needed for the drug or metabolite to be present in urine), more flexibility is appropriate to accommodate situations where specimen collectors are not immediately available. This change is intended to accommodate situations where no collection personnel are on site and need to be called in or the individual needs to be transported to another location for testing. However, to assure that collection and testing is not delayed to the point where results would be compromised, the revision establishes the maximum time that testing may be delayed. A shorter delay time is provided for alcohol to account for the faster metabolism of alcohol by the body.

Licensee Cost Reduction/Increase: These revisions are expected to provide indeterminate savings, by reducing the need to call in collection personnel, or the need to transport the individual being tested to another location.

Backfit Rule Considerations: The current rule at section 26.24(a)(3) requires that specimens be collected for "for-cause" testing "as soon as possible" following several described conditions. This revision adds flexibility to the timeliness of those existing requirements, and is a permissive relaxation because licensees can continue to conduct the tests "as soon as possible" which has been interpreted and enforced as a prompt reaction.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

Section 26.24(f): MRO to complete review as soon as practicable and inform management if determination of test result is delayed more than 14 days after collection instead of completing review and notifying within 10 days after screening test

Revision: This revision for section 26.24(f) [section 26.24(e) in the current rule] would provide a relaxation of the current 10-day requirement for reporting of MRO review results, by requiring MROs to report results of their reviews "as soon as practicable." This revision would also state that, in cases when MROs have not completed their reviews within 14 days of specimen collection (as opposed to 10 days after the initial presumptive positive screening test results as currently required), MROs would be required to report the status of their reviews to licensee management at that time and make appropriate recommendations for dealing with the situation.

Purpose: Section 26.24(e) [section 26.24(f) in the revised rule] currently requires MROs to complete their reviews of test results and notify licensee management of the outcome of their reviews, within 10 days after the original positive screening test results that prompted further testing and the subsequent MRO review. The intent of the current requirement is to ensure that results are obtained within a reasonable time after specimen collection. However, industry experience has indicated in some cases that the current requirement is impractical. This revision will provide MROs with additional time to review test results consistent with a "worst case" situation and will create consistency in MRO reporting periods across the industry. Because the "clock" starts with the initial presumptive positive screening test, licensees conducting onsite testing have 2 to 3 days less time to complete the MRO reviews than the rest of the licensees. The "collection of a specimen" standard will establish a more consistent and controllable time line than the current "initial screening test" standard and the licensees conducting initial screening tests on-site will then have the same amount of time to review the HHS-certified laboratories' reports as do those licensees not conducting on-site testing. Experience has shown that the majority of certified laboratories take only 1 to 3 days from receipt of a specimen to screen and confirm tests; isolated exceptions are usually caused by 6 acetylmorphine (6-AM) testing and occasionally by unusual technical problems.

Licensee Cost Reduction/Increase: Some indeterminate savings are anticipated.

Backfit Rule Considerations: The proposed requirement that MROs report the status of their reviews of FFD policy violations to licensee management within 14 days of specimen

collection would be a slight relaxation of the current test result reporting requirements. It would also provide a start date for the reporting period that could be more easily determined by licensees than is currently the case. Licensee management must be made aware of test results or other indications of questionable worker fitness as soon as practicable in order to take timely action to prevent potential safety concerns.

NEI objected to the requirement for the MRO to report the status within 14 days when the MRO has been unable to come to a final decision. In NEI's view this requirement would add excessive regulatory burden and be too prescriptive. The NRC staff disagrees; the revision is a relaxation from the current rule that requires the MRO review be completed and management notified within ten days. This original requirement was meant to assure that a worker with questionable fitness would not have continued access for an unlimited period without management being able to determine whether the situation presents a safety concern.

Staff Conclusion: This revision is not a backfit because: (a) it is a permissive relaxation of a current requirement concerning the timeliness of the reviews of test results, and (b) it clarifies the point in the testing process at which the clock begins running for determining the timeliness of the MRO review.

Section 26.24(i): Flexibility for unusual medical conditions

Revision: A new section 26.24(i) would address cases where an individual has a medical condition that makes collection of breath, blood, or urine specimens difficult or hazardous. The MRO, in consultation with the worker's treating or private physician, would be authorized to determine a method of specimen collection provided the methods chosen can achieve comparable results.

Purpose: Appendix A of the current rule sets forth the requirements for the collection of urine specimens for determining the presence of drugs and the measurement of a breath specimen to determine the presence of alcohol for all tests required by section 26.24(a). No alternatives are provided in the Appendix to address situations where the collection of the standard specimen was difficult or hazardous. This revision is intended to address questions raised by FFD program managers regarding appropriate actions on occasions where an individual has a medical condition that makes collection of breath, blood, or urine specimens difficult or hazardous. Although such occasions are anticipated to be rare, the first concern should, in all cases, be the health and safety of the individual. Drug and alcohol testing should be done when reasonably possible using the best techniques available under the circumstances.

Licensee Cost Reduction/Increase: There are no discernable cost impacts or benefits.

Backfit Rule Considerations: This revision is intended to provide guidance in situations that were not considered during the development of the original rule. The change does not impose any additional burden on licensees and clarifies how licensees are to react to unusual circumstances.

Staff Conclusion: This revision is not a backfit because: (a) it clarifies, but does not change, a current requirement and (b) it is a permissive relaxation of a current requirement.

Section 26.27(a): Certain aspects of fitness history to be limited to 5 years

Revision: A revision to section 26.27(a) would require licensees to obtain a written statement from individuals about their substance abuse history for the 5 years preceding employment with the licensee. This information provides the basis for the suitable inquiry, required by the current section 26.27(a)(2).

Purpose: The current section 26.27(a)(1) requires a written statement from the individual about whether they "were ever" denied "activities within the scope of [part 26]" because of a fitness/substance abuse history. However, the current rule does not require the individual to disclose any substance abuse in the past five years, but the definition of suitable inquiry requires licensees to determine if the person was tested positive for illegal drugs. This revision would require individuals to disclose information about substance abuse in the preceding five years. This requirement is also consistent with the NRC's access authorization rule (which requires a background check of five years) and sets a reasonable standard for the length of time the fitness history should encompass.

This revision is also related to other revisions to this section discussed under Group IIA, fitness history need not be obtained for absences of 30 days or less, and Group IIIB, clarifying and conforming edits.

Licensee Cost Reduction/Increase: There are no discernable cost impacts or benefits.

Backfit Rule Considerations: NEI argued that this proposed change should be considered a backfit unless the Commission adopted two additional revisions to this section that it proposed. First, NEI recommended that this section be further amended to allow licensees to grant temporary unescorted access similar to that provided for by the

access authorization rule. NEI's recommended revision would authorize licensees to grant such access pursuant to a suitable inquiry into the applicant's activities over the past year. This one-year suitable inquiry would be conducted while the licensee is implementing the full five-year suitable inquiry for the purpose of eventually granting permanent unescorted access. NEI's second recommended revision would authorize licensees to grant temporary unescorted access to employees upon completion of the one-year suitable inquiry, or at least a demonstration of a best-efforts attempt to complete it. Although NEI's written rationale for this recommendation was somewhat unclear, NEI has stated that it believes that licensees should be authorized to grant temporary unescorted access upon the initiation, rather than the completion, of the one-year suitable inquiry.

Insofar as NEI's proposed change is related to the access authorization program required by 10 CFR 73.56, it should be noted that the FFD rule currently envisions that whatever the NRC accepts for temporary access under the access authorization rule will also apply to the granting of temporary access under section 26.27. However, there has appeared to be continuing lack of clear understanding on this within the industry. Therefore, the staff recommends that section 26.27 be conformed to the access authorization rule in response to public comments. The FFD rule currently requires a best-effort verification of substance abuse history for the past five years before unescorted access can be granted. While the FFD rule currently does not explicitly provide for the granting of temporary access, the access authorization rule at 10 CFR 73.56(c)(2) permits temporary unescorted access authorization. The staff has in the past indicated to licensees that temporary unescorted access can be granted when the past year's suitable inquiry results have been received and evaluated or best efforts documentation completed, the balance of the five years inquiry has been initiated, and the provisions of paragraph 6.4 of Regulatory Guide 5.66 (which all licensees have committed to implement and have as a condition of their license) have been met. Consistent with that guidance, the staff is now proposing a new section 26.27(a)(6) that would provide for the granting of temporary unescorted access under these conditions. The staff's proposal encompasses, and is consistent with, both NEI recommendations described above, and current access authorization program requirements. Accordingly, it would appear that NEI would not consider this change to be an objectionable backfit.

Staff Conclusion: The revision requiring an individual to provide a statement of fitness history for the past 5 years is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because: (a) it would provide additional information on an individual's past substance abuse history, and (b) the industry does not appear to consider this an

objectionable backfit, given other changes that the staff is proposing to make in the area of temporary access which are consistent with NEI suggestions.

Section 26.27(a): Power reactor licensees usually need not obtain statements responding to activities related to possession or transport of Category I nuclear material

Revision: This revision to section 26.27(a) would clarify that power reactor licensees do not have to obtain statements from individuals about activities involving the possession or transport of Category I nuclear material unless the background investigation indicates that the individual has been employed by a licensee authorized to possess or transport such material.

Purpose: This revision would avoid the need for the licensee to obtain statements from individuals who have not been involved in the possession or transport of Category I nuclear material as is currently required by section 26.27(a)(1)(iv) through (vi).

Licensee Cost Reduction/Increase: Some indefinite savings may accrue, because applicants for unescorted access at power reactors would not need to answer irrelevant questions about their past employment.

Backfit Rule Considerations: This is a relaxation of requirements.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 26.27(c): Change reference to records retention requirements (former title: Allow records of FFD violations to be discarded after 5 years)

Revision: Section 26.27(c) would be revised to change the referenced requirements from section 26.27(a) which concerned suitable inquiries, to section 26.71(c), which concerned the retention of records pertaining to FFD policy violations resulting in revocations of activities covered by the rule.

Purpose: The current section 26.27(c) requires licensees to retain records of FFD policy violations other than positive test results for the purpose of meeting the requirements of section 26.27(a), which concerns suitable inquiries. No specific record retention period is specified, although section 26.71(c) states that records of persons made ineligible for activities covered by the rule (e.g., revocation of access) must be retained until the Commission terminates the license. The proposed rule would have reduced the records

retention period to five years. Public comments indicated that all records of FFD policy violations should be retained in order for the licensees to comply with the suitable inquiry requirements of section 26.27(a). The staff has reconsidered its original recommendation and decided that the original record retention requirements (i.e., in section 26.71(c) to retain until license termination) are appropriate, and that section 26.27(c) should reference section 26.71(c) to clearly and directly state the records retention requirements.

Licensee Cost Reduction/Increase: This revision will have no cost impact.

Backfit Rule Considerations: Section 26.71(c) had always required licensees to retain records of violations that resulted in revocation of access until the Commission terminated the license. The change in the referenced requirements in section 26.27(c) to section 26.71(c) is a minor administrative change that clarifies the proper record retention requirements.

Staff Conclusion: This revision is not subject to backfit requirements because it is an administrative change.

Section 26.29(b): Permit provision of personal information for judicial or administrative proceedings initiated by the subject individual

Revision: This revision to section 26.29(b) would allow disclosure of personal information collected in compliance with the rule to presiding officers of judicial or administrative proceedings that are initiated by the person who is the subject of the information.

Purpose: The current section 26.29(b) prohibits the disclosure of information collected in compliance with the rule except to those with a legitimate need for the information; the rule provides such a list. This revision would eliminate the need for the staff to process exemptions to permit licensees to provide such information. This revision would allow disclosure to, for example, state agencies investigating whether the firing of an employee was justified in order to determine unemployment compensation entitlements. The disclosure would be permissible as long as the employee initiated the proceeding.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: The revision, by permitting presiding officers of judicial and administrative hearings initiated by the subject individual to have access to the personal information, is a permissive relaxation of a current requirement. Experience in implementing the rule indicates that the rule omitted presiding officers of judicial and

administrative hearings who also have a legitimate need for access to the information and concerns about maintaining the privacy of individuals is less of a concern where the individual initiated the judicial or administrative proceeding.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

Section 26.29(b): Permit provision of personal information to contractors and vendors

Revision: Section 26.29(b) would be revised to permit the licensee to provide to contractors and vendors personal information regarding the licensee's unescorted access decisions with respect to the contractor's or vendor's employees.

Purpose: Section 26.29(b) does not currently permit licensees to provide to contractors and vendors information concerning the reasons for denying unescorted access to vendors' and contractors' employees. However, under section 26.23(a)(2) contractors and vendors may not assign individuals with a known history of substance abuse or who have been denied unescorted access under Part 26 to work within the scope of Part 26 without the knowledge and consent of the licensee. This revision would permit contractors and vendors to obtain information concerning unescorted access decisions on their employees made by licensees, and thereby assure proper implementation of section 26.23(a)(2).

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: This corrects the existing requirement in Section 26.29(b), and is necessary to assure that contractors and vendors comply with the requirements of section 26.23(a).

Staff Conclusion: This revision: (a) is an administrative change, and (b) fits within the Backfit Rule's compliance exception.

Section 2.2(a) of Appendix A: Reduce time for retention of chain-of-custody forms showing violations

Revision: This revision to section 2.2(a) of Appendix A would revise the current requirement that all chain-of-custody forms be retained as a permanent record. The change would permit licensees and the HHS-certified laboratories to dispose of chain-of-custody forms associated with FFD policy violations after the requirements of section

26.71(b) and (c) are met, and to dispose of chain-of-custody forms recording no violation after appropriate summary information is recorded for program administration purposes. Minor conforming changes were made to this revision in accordance with the revisions to section 26.27(c), discussed in Group IIB, above.

Purpose: The intent of this revision is to allow chain-of-custody forms to be disposed of after they have no further purpose. Modifications to this revision are proposed in the final rule package [in conjunction with changes to section 26.27(c)] to assure that this relaxation does not result in the disposal of records needed to respond to suitable inquiry or for legal proceedings.

Licensee Cost Reduction/Increase: Annual industry-wide savings would be an estimated \$851,000. (Note: this revision should have been included under Group IIA since it has quantitative monetary benefits.)

Backfit Rule Considerations: This is a permissive relaxation of current requirements in section 2.2(a) of Appendix A to retain chain-of-custody forms until termination of the license.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 2.4(g)(13) of Appendix A: Allow licensees to set temperature range within rule limits

Revision: This revision of section 2.4(g)(13) would allow licensees to set their own parameters, within the range set by the rule, of the urine temperature range for acceptable urine specimens. (A related revision to this section that narrows the acceptable temperature range is discussed in Group IIIA, below.)

Purpose: Section 2.4(g)(13) of Appendix A currently sets a temperature range for an acceptable urine specimen. The temperature range is one of the current requirements designed to deter or detect subversion of the testing process, particularly the submission of a surrogate sample. Under this revision, the temperature range would be left up to each licensee to designate, but it would have to be within a band of 3° C/6° F or less, with a lower limit of not less than 34°C/94° F. Each licensee would be able to set its own temperature band to fit the particular urine temperature measuring device it uses in conjunction with the collection site's environment-specific conditions. Since the FFD rule was published in 1989, there have been improvements in urine temperature measuring

devices. This revision would allow licensees to choose the particular temperature measurement devices that best meet their needs.

The increased flexibility recognizes that there are a number of acceptable options for recording temperature and that each allows different minimum and maximum acceptable readings. For example, some temperature recording devices are located in the specimen container and record a "peak" temperature immediately. The temperature that is expected to be recorded by this device is close to core body temperature--a temperature that could occasionally require a second specimen under direct observation with the temperature range under the current rule. The current temperature requirement is based on a method that records the temperature several minutes after the specimen leaves the body. That introduces many factors that influence the results, e.g., ambient temperature, volume of the specimen, time of temperature measurement after voiding, size of and material used in the collection cup, etc. The range of temperatures (i.e., the spread between the minimum and maximum acceptable temperatures) must be limited as specified in the rule. The type of temperature reading device, and the acceptable range of temperature for that device, must be specified in the licensee's procedures. This relaxation would not be consistent with the HHS Mandatory Guidelines.

Licensee Cost Reduction/Increase: There may be some indeterminate savings afforded since licensees would have a greater range of temperature measuring devices to choose from and the capability to select measurement devices which are suited to the environmental conditions of the collection site.

Backfit Rule Considerations: The current rule in section 2.4(g)(13) of Appendix A establishes a temperature range for an acceptable specimen. This revision would permit licensees to adjust the temperature range to be compatible with a wide variety of temperature measuring devices and methods that are now available. The revision would increase the flexibility that licensees currently have in choosing temperature measurement devices. In doing so, this revision would tend to reduce the regulatory burden on licensees.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 2.4(g)(24) of Appendix A: MRO or other designated medical person can authorize an observed collection

Revision: Section 2.4(g)(24) of Appendix A currently requires that "a higher level supervisor in the drug testing program" must review and concur with a decision by a collection site person to obtain a urine specimen under direct observation. This section would be revised to add the MRO or other designated medical professional as parties that could participate in these decisions.

Purpose: The industry's experience in making decisions to obtain urine specimens under direct observation has shown the current rule language to be unnecessarily restrictive. MROs or other medical professionals are qualified to participate in these decisions and this section should be revised to reflect that fact.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: The current rule in section 2.4(g)(24) of Appendix A requires supervisory approval prior to obtaining a urine specimen under direct observation. This requirement was established to prevent indiscriminate collections of urine specimens under direct observation. The staff has determined that the current requirement is overly restrictive and that the medical professionals in the FFD staff can participate in those decisions. This added flexibility will reduce burden.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 2.4(j) of Appendix A: Flexibility on licensee internal reporting and actions when individual fails to cooperate

Revision: Section 2.4(j) of Appendix A is currently somewhat restrictive regarding to whom collection sites must report incidents when employees refuse to cooperate in the testing process. This revision would allow such incidents to be reported to an appropriate authority, as designated by the licensee, rather than through the MRO to appropriate management.

Purpose: The current language of Section 2.4(j) in Appendix A makes the MRO the key person in having these incidents reported to licensee management. This revision would recognize that the MRO may be, but need not be, a key player because refusals to cooperate are administrative concerns rather than medical problems, and in many cases

the MRO may not be readily available. This revision is consistent with who must be contacted to resolve collection problems also addressed in the revision to section 2.4(g)(24), discussed immediately above.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: The current rule requires that failure to cooperate be reported to the MRO, who, in turn, is required to report to appropriate management. The staff has determined that the current requirement is overly restrictive and that licensees should be given the flexibility as to whether the MRO should be included in the reporting/decision making process.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 2.7(c) of Appendix A: Flexibility in means of keeping specimens chilled

Revision: A revision to section 2.7(c) of Appendix A would allow licensees to provide for contingency measures to be available to maintain specimens in a chilled state during a power failure rather than specifically require emergency power equipment to respond to these events.

Purpose: The original requirement for emergency power was an adaptation of HHS requirements for testing laboratories that has been determined to be unnecessary at nuclear power plants and Category I licensees. Because of the smaller volume of specimens stored at nuclear power plants and Category I licensees (usually fewer than 50, frequently fewer than 20) compared to a drug testing laboratory (several thousand specimens), the nuclear power plant and Category I licensees should be able to implement contingency measures, such as putting ice or dry ice in the refrigerator; that would be impractical at a testing laboratory. Furthermore, refrigerated specimens would not show any appreciable deterioration for a number of hours, which means that immediate restoration of power is not necessary if contingency measures can be implemented.

Licensee Cost Reduction/Increase: No significant cost impact.

Backfit Rule Considerations: The current rule in section 2.7(c) of Appendix A requires that emergency power equipment be available to maintain specimens in a chilled state in case of a power failure. The purpose of this requirement was to assure that specimens did not

degrade and cause false negative test results. The staff has determined that the current requirement is overly restrictive to the licensees and that alternative measures could be taken to assure that the specimens remain in a chilled condition.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

Sections 2.7(f) and (g) of Appendix A: When licensee uses more stringent cut-off levels, tests at level set by the rule can be calculated and need not be conducted

Revision: Sections 2.7(f) and (g) of Appendix A would be revised to clarify that licensees using lower cut-off levels are not required to perform two different tests at different cut-off levels. Instead, they should use standard extrapolation methods.

Purpose: Licensees who choose to test at lower cut-off levels than specified by the rule are required in section 2.7(f)(1) [currently section 2.7(e)(1)] and section 2.7(g)(2) [currently section 2.7(f)(2)] to report results of tests at both levels (i.e., the lower cut-off level and the level specified by the rule). The intent was for licensees to have the results of the test at the lower cut-off level used to extrapolate what the results would have been at the NRC standard cut-off level. However, some licensees interpret the rule to require two separate tests. The revision is intended to clarify the original expectation.

Licensee Cost Reduction/Increase: Some cost savings to licensees currently performing two tests could result.

Backfit Rule Considerations: The current rule in sections 2.7(f) and (g) permits licensees to use more stringent cut-off levels than specified in the rule, and when more stringent cut-off levels are used, licensees are required to report the results for both cut-off levels. The purpose of this requirement was to collect data to justify the use of lower cut-off levels. It was never intended to cause two separate tests to be conducted. The staff has determined that the current requirement needs to be clarified, and some flexibility provided.

Staff Conclusion: This revision is not a backfit because a) it clarifies, but does not change, a current requirement and b) it is a permissive relaxation of a current requirement.

Section 2.7(h) of Appendix A: Reduce time for laboratories to report results

Revision: Section 2.7(h) of Appendix A [currently section 2.7(g)] would have been revised to require HHS-certified laboratories to report test results to licensees in four working days.

Purpose: Currently, section 2.7(g) requires a HHS-certified laboratory to report the results in five working days. The purpose of the change was to allow the licensee to take more timely action against the individual who tested positive.

Licensee Cost Reduction/Increase: There would likely have been no cost associated with the change, since most test results are reported sooner than four working days.

Backfit Rule Considerations: Commenters objected to this change because it would create a difference between the NRC and HHS rules without any compelling reasons for the disparity. Upon reconsideration, the Staff agrees with the commenters and has decided to withdraw the proposed revision, .

Staff Conclusion: Not applicable. .

Section 2.7(n) of Appendix A: Allow licensee to use another HHS-certified laboratory when its original laboratory loses its certification (formerly: Flexibility provided if lab loses certification)

Revision: Section 2.7(n) [currently section 2.7(m)] of Appendix A would be revised to permit, in the event a licensee's HHS-certified laboratory loses its certification, the licensee to use, for up to 3 months, another HHS-certified laboratory that has been audited by another NRC licensee that shares the same drug testing and cutoff standards.

Purpose: The current rule in section 2.7(m) requires licensees to perform pre-award inspections and evaluation of a HHS-certified laboratory's testing procedures prior to the award of a contract for FFD testing. When a laboratory loses its HHS certification, licensees are suddenly left without the capability to implement the specimen testing portion of their program. The process of selecting a new laboratory and conducting pre-award audits takes considerable time, during which licensees will be without laboratory services. The current regulations do not afford any flexibility with respect to the need to perform pre-award inspections and evaluations. This revision would provide the licensee with some flexibility to maintain a specimen testing process when the licensee's laboratory loses its HHS certification.

Licensee Cost Reduction/Increase: Some non-quantifiable cost savings in these relatively infrequent circumstances would result.

Backfit Rule Considerations: On a few occasions, a laboratory lost its certification and a licensee needed to establish an immediate contract with another laboratory to perform testing. This revision would provide licensees with flexibility in initiating a new contract by "accepting" the audit by another licensee.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 2.7(p) of Appendix A: Flexibility to use old or new NHTSA standards for breath analysis equipment

Revision: A revision to section 2.7(p) of Appendix A [section 2.7(o)(3)(ii) of Appendix A in the current rule] would allow licensees to use evidential-grade breath alcohol analysis devices that conform with the National Highway Traffic Safety Administration (NHTSA) standards published in December 1984 or September 1993, or as those standards are subsequently amended.

Purpose: Section 2.7(o)(3)(ii) currently directs licensees to use the 1984 NHTSA-certified evidential-grade breath alcohol analysis devices to ensure accurate and fair test results. NHTSA subsequently published new standards in 1993. This revision would recognize the new standards, but would allow licensees to continue to use breath alcohol analysis devices that conform to the 1984 standards (as well as future NHTSA standards), if they choose to do so.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: This section currently requires licensees to use NHTSA-certified evidential-grade breath alcohol analysis devices that meet 1984 NHTSA standards. This revision would allow licensees the latitude to use devices certified to the 1984 standards, the 1993 standards as well as devices that NHTSA may certify in the future.

NEI asked the NRC to relax section 2.7(p)(3)(ii) requirements to allow the use of non-evidential screening devices for initial alcohol screen tests. No backfit issue is raised by NEI's request. Instead, it is a comment on the use of non-evidential screening devices. The NRC has considered and rejected requests in the past that non-evidential screening

devices be allowed for initial alcohol screen tests because their performance has not been verified sufficiently by NHSTA.

Staff Conclusion: This revision is not a backfit because it is a relaxation of a current requirement.

Section 2.8(f) of Appendix A: Allow disposal of records of investigative findings after 3 years

Revision: A revision to section 2.8(f) of Appendix A would allow licensees to dispose of records of investigative findings concerning testing errors and other unsatisfactory laboratory performance after three years.

Purpose: Unlike similar sections in the current Part 26 rule that allow licensees to dispose of certain types of records after a specified period, section 2.8(f) is now silent as to whether or when licensees can dispose of records of investigative findings. Thus, the implication is that the records must be retained until the end of the license. There is no practical reason why licensees should retain these records for such a long period of time. This revision would relieve licensees of having to do so by defining a 3-year retention period after which they can dispose of these records.

Licensee Cost Reduction/Increase: There may be some minimal cost saving.

Backfit Rule Considerations: As currently written, this section does not specify whether or when licensees may dispose of investigative records concerning testing errors and other unsatisfactory laboratory performance. This revision would relax this records retention requirement by defining a 3-year retention period after which licensees may dispose of the records. By doing so, it would create a permissive relaxation of regulatory burden. Licensees would be free to retain records for longer periods. The CRGR Charter states that new or revised information collection and reporting requirements are not considered to be backfits.

Staff Conclusion: This revision is not a backfit because: (a) it is an information collection and reporting requirement, and (b) it is a permissive relaxation of a current requirement.

Section 2.9(d) of Appendix A: Delete requirement for MRO determination of clinical evidence of legal drugs

Revision: Section 2.9(d) of Appendix A would be revised to delete the current requirement that MROs are to determine whether there is clinical evidence, in addition to the urine test results, of the misuse of legal drugs that are commonly prescribed or commonly included in over-the-counter preparations (e.g., benzodiazepines or barbiturates).

Purpose: The current requirement in Section 2.9(d) regarding clinical evidence of the unauthorized use of legal drugs should be deleted because, as experience in implementing the rule and public comments indicate, licensees have had certain technical difficulties in complying and it introduces too much ambiguity into the rule's requirements.

Licensee Cost Reduction/Increase: There would be no significant cost impact.

Backfit Rule Considerations: This revision would create no new requirement. Instead, it would reduce this section's current regulatory burden by eliminating the MRO's responsibility to seek clinical evidence of the unauthorized use of certain drugs.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

NEW: Section 2.9(d) of Appendix A: Increase flexibility in defining clinical signs of opiate abuse

Revision: A revision to section 2.9(d) of Appendix A would make behavioral and psychological signs of acute opiate intoxication or withdrawal part of the clinical evidence that MROs should look for when determining whether an FFD policy violation involving opiates has occurred. This change increases the flexibility in the definition of clinical evidence of drug use.

Purpose: Section 2.9(d) currently requires MROs to determine that there is clinical evidence of unauthorized use of any opium, opiate, or opium derivative, in addition to the urine test result, before verifying a confirmed positive test result for opiates. It currently mentions only recent needle tracks and behavioral or psychological signs of acute opiate intoxication or withdrawal as examples of such clinical evidence. The revision would expand the examples of clinical evidence provided by this section by, for example, allowing MROs to use the admission of opiate abuse as a clinical sign of abuse.

Licensee Cost Reduction/Increase: There would be no significant cost impact.

Backfit Rule Considerations: This revision to Section 2.9(d) of Appendix A would not change the current requirement that MROs seek clinical evidence of opiate abuse before verifying a confirmed positive test result for opiates as an FFD policy violation. The revision would provide increased guidance by expanding the examples of conditions that MROs can consider to be evidence of opiate abuse.

Staff Conclusion: This revision is not a backfit because it creates no new requirement.

Section 2.9(h) of Appendix A: Allow disposal of records of negative test results, based on scientific insufficiency, after 3 years

Revision: Section 2.9(h) [currently section 2.9(g)] of Appendix A would be revised to allow licensees to dispose of findings of negative test results based on scientific insufficiency after three years.

Purpose: Section 2.9(g) currently states that licensees shall maintain these records but does not tell licensees when they may be discarded. This revision would reduce regulatory burden by defining a 3-year retention period after which licensees are free to discard the records.

Licensee Cost Reduction/Increase: Because there are few of these records, this change will produce only minimal cost reductions.

Backfit Rule Considerations: Section 2.9(g) currently states that licensees shall maintain these records but does not tell licensees when they may be discarded. This implies that the records must be kept until the end of the license. This revision would reduce regulatory burden by defining a 3-year retention period after which licensees are free to discard the records. However, licensees would be free to retain records for longer periods.

Staff Conclusion: This revision is not a backfit because it is a permissive relaxation of a current requirement.

GROUP III: OTHER WORTHWHILE CHANGES

A. Improvements based on experiences that the NRC believes are needed and proposes to adopt.

Section 26.24(a)(5): Require return-to-duty testing after extended absences or denial of access

Revision: A new section 26.24(a)(5) would be added to clearly state that personnel returning to work after extended absences or after having been denied access under section 26.27(b) must be tested before regaining unescorted access. The section would also allow a negative test meeting Part 26 standards performed within the previous 60 days to serve as a return-to-duty test unless the employee has previously been denied access under section 26.27(b).

Purpose: With respect to the personnel returning to work after extended absences, the staff is aware that most, but not all, licensees are already conducting testing of individuals returning to work after extended absences. The failure of these few licensees who are not now doing such testing indicates a need to establish clear return-to-duty testing requirements. From its inception, sections 26.2(a) and 26.24(a) have been interpreted to require that individuals covered by the rule are subjected at all times to various provisions of the rule, such as behavioral observation and being tested when randomly selected. If an individual was not subject to behavioral observation and random testing, a pre-access test was required upon return. Licensee understanding of this requirement is evident from question number 7.3 of NUREG-1385, in which a licensee asked if licensees may suspend access of individuals having infrequent access between on-site assignments, pending pre-access testing on each return to the site.

With respect to individuals returning to work after having been denied access under Section 26.27(b), that section currently requires satisfactory management and medical assurance of fitness before an individual may be permitted to perform activities covered by the rule. A demonstration that the individual is free of drugs (i.e., a test) was deemed part of the medical assurance of fitness. As with the case of individuals returning to work after extended absences, not all licensees are conducting testing of individuals returning to work after having been denied access under Section 26.27(b). This shows the need to establish clear return-to-duty testing requirements covering such individuals.

This section would provide licensees flexibility in conducting such testing by allowing a negative test meeting Part 26 standards performed within the previous 60 days to serve

as the return-to-duty test required by current section 26.27(b)(4) unless the employee has previously been denied access under section 26.27(b).

Licensee Cost Reduction/Increase: There would be some increased cost for the few licensees who are not testing personnel returning to work after extended absences or after having been denied access under section 26.27(b). There would be some unquantified cost savings by accepting negative tests conducted during the previous 60 days to serve as a return-to-duty test.

Backfit Rule Considerations: This revision clarifies the NRC's original intent that people covered by the rule must be subject to its provisions at all times, and if they are not subject to behavioral observation and random testing they need to be tested upon return. Furthermore, the revision clarifies the NRC's original intent that testing is part of the medical assurance of fitness. The revision is consistent with current industry general practice of testing employees in these circumstances. The provision on testing of persons returning to work after having previously been denied access also responds to the Commission's March 27, 1991 SRM which directed the staff to provide more explicit testing requirements following a drug test. The provision with respect to return-to-duty testing would reduce licensee burdens by allowing a licensee to credit a negative test performed within 60 days to serve as a return-to-duty test, thereby avoiding the need to perform a second test for access.

***Staff Conclusion:* The changes with respect to testing personnel returning to work after extended absences or after having been denied access under section 26.27(b) is a worthwhile revision that the staff recommends for adoption as an exception to the Backfit Rule because it would assure: (a) that persons removed for being unfit for duty would be tested and determined fit before being returned to duty, and (b) that persons returning after extended absences are fit for duty. The change with respect to accepting negative tests conducted within 60 days as a return-to-duty test is not a backfit because it is a permissive relaxation of a current requirement.**

Section 26.24(d)(1): Require on-site testers to determine validity of specimens on site

Revision: Section 26.24(d)(1) would be revised to assure that invalid specimens are identified in on-site testing programs. This revision is a conforming change which is associated with new section 2.7(e) of Appendix A, which is discussed in Group I above.

Purpose: Section 26.24(d)(1) currently allows licensees to screen test urine specimens at their own on-site testing facilities. The validity testing required by the new section 2.7(e)

is aimed at preventing subversion of the testing process by detecting specimen adulteration or dilution. The change to section 26.24(d)(1) restates and reinforces this validity testing requirement. It indicates how licensees are to comply with the rule's current requirement to determine specimen validity, to ensure the proper testing of specimens on site, and to prevent premature disposal of questionable specimens.

Licensee Cost Reduction/Increase: This revision will create no new costs beyond those that licensees are currently incurring to determine specimen validity.

Backfit Rule Considerations: The Commission explicitly expressed its intent in the original rule in section 2.4(g) of Appendix A that licensees must take precautions to ensure that specimens are not adulterated or diluted and that authentic specimens are collected, in sections 2.1(b) and (c) which permit testing of specimens for adulterants, and in section 2.7(d) which permits special processing (meaning testing to limit of detection) of specimens suspected of being adulterated or diluted. Despite these requirements, some licensees that conduct on-site testing are not determining specimen validity to detect adulteration or dilution. This revision will bring those licensees into compliance with the Commission's original intent. It will reiterate these already existing requirements and sets forth the best means of determining specimen validity by those licensees conducting on-site testing.

***Staff Conclusion:* This revision fits within the Backfit Rule's compliance exception and is necessary to achieve an original purpose of the rule to "take precautions to ensure that a urine specimen is not adulterated or diluted ... that authentic specimens are obtained"**

Section 26.24(h): Require back calculations for BACs between 0.02 and 0.04

Revision: A revision to section 26.24(h) [section 26.24(g) in the current rule] and the proposed addition of section 2.9(h) to Appendix A would have required licensees to use a calculation technique known as "back extrapolation" to determine whether an employee had an impermissibly high blood alcohol concentration (BAC) when reporting for work or at some time during the work shift. Public commenters pointed out that using back extrapolation could be somewhat complicated and lead to unnecessary difficulties in defending an FFD policy violation based on a back extrapolation result.

Therefore, the staff is recommending that the proposed back extrapolation requirement not be adopted. In its place the staff recommends a revision that would require that an alcohol confirmatory test showing a BAC of 0.02 percent or greater after the employee

has been at work for two or more hours or a BAC of 0.03 percent or greater after the employee has been at work for more than one hour be declared a positive result for alcohol.

Purpose: Section 26.24(g) currently requires that a blood alcohol concentration (BAC) of 0.04 percent or greater must be considered to be a positive test result. However, the body rapidly metabolizes alcohol (approximately 0.015 percent/hour), so that a person tested late in the shift (typically 8-12 hours) could show a BAC of less than 0.04 percent even though during their shift the BAC was greater than 0.04 percent. Many licensees were "back extrapolating" or "back calculating" to determine if the employee had been over 0.04 percent BAC at any time during the work tour. However, some licensees didn't consider the rapid metabolism of alcohol into their determination and ruled the result negative so long as the BAC level was below 0.04 percent at the time of testing. Workers took advantage of this licensee practice by delaying reporting for testing after having been called for testing, by which time the worker hoped that BAC levels were below the 0.04 cutoff level due to metabolism during the period of delay. The Commission requested that the "back extrapolation" approach be adopted in an SRM dated March 27, 1991. However, the staff now recommends that the Commission adopt a different approach because of the technical difficulties and issues associated with back-extrapolation.

The new revision would provide licensees with a specific, technically defensible procedure for determining whether the tested person has had a BAC of 0.04 percent or greater at any time during the work shift. Although having that high a BAC during the work shift is a violation of FFD policy (because section 26.10 requires licensee programs to assure that workers are not under the influence and the rule establishes a legal presumption of impairment when the BAC is 0.04 percent or above), the rule currently provides little or no guidance for licensees on how to determine violations when the test is administered some time into the donor's workday and the alcohol has been metabolized to some extent. Using the absence of such regulatory guidance, some licensee employees have been avoiding detection of alcohol abuse by using the relatively rapid rate at which alcohol is metabolized and delaying testing until their BAC levels are below the 0.04 percent cutoff level. This revision would provide a simple and technically defensible means of detecting alcohol violations, and would respond to the Commission's SRM.

Licensee Cost Reduction/Increase: This revision will create no new costs, and will provide indeterminate savings for many licensees through the direct use of test results which will eliminate the need for an examination by the MRO and calculation, plus reduced probability of the results being challenged.

Backfit Rule Considerations: This revision clarifies the Commission's original intent in section 26.10 that workers not be impaired while at work, and clarifies how that will be accomplished with respect to detection of alcohol several hours into a tour of duty. To the extent that some licensees are not currently declaring positive those test results that indicate the tested person was above the BAC level earlier in the tour, this revision will bring those licensees into compliance.

Commenters, including NEI, contended that there would have been a number of problems with using back extrapolation. Many commenters thought that the use of extrapolation would be technically difficult and undesirable from a policy perspective. In addition, because of the potential technical problems involved, NEI recommended against basing serious disciplinary actions on back extrapolation. No backfit issue per se is raised by NEI's comment. Instead it is a comment on the proposed requirement for back extrapolation. The staff has decided to withdraw the proposed back extrapolation requirement. Instead the staff proposes a rule revision that would accomplish the purpose of back extrapolation but do so in a way that would create no new burden on licensees. Rather than requiring the MRO to be involved in a somewhat complicated means of extrapolating prior BAC, the staff now proposes that the FFD rule contain specific cutoff levels based upon the time that a worker has been at work prior to the BAC test. Thus, the licensee would simply compare the BAC results to the applicable BAC cutoff level for the time period that the worker has been at work.

The revised approach, as currently proposed by the staff, is technically defensible, would decrease burden for the majority of licensees that currently perform back-extrapolation, and would not create any new costs to other licensees. Collection site personnel would have a routine means of determining whether particular alcohol confirmatory test results should be declared either positive or negative and would not need to involve the MRO to perform the back calculation.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would ensure workers are not impaired from alcohol while at work, and would provide a simple process of obtaining that assurance.**

Sections 26.27(b)(3) and (4): Minimum sanctions for violations of FFD policy resulting from alcohol abuse or the use of alcohol within the protected area

Revision: Sections 26.27(b)(3) and (4) have been revised to establish specific sanctions for positive alcohol test results and for the use of alcohol within the protected area.

Purpose: Section 26.27(b)(5) currently requires licensees to impose sanctions for misuse of alcohol that are sufficient to deter abuse of legally obtainable substances as a substitute for abuse of proscribed drugs, but does not provide specific sanctions for FFD violations involving alcohol. The staff is aware that some licensees exact sanctions for alcohol violations that are significantly less stringent than for confirmed evidence of drug abuse. In the staff's view, that level of sanctions for alcohol positives does not adequately deter alcohol abuse and, therefore, does not meet the general performance objectives of the rule, as described in section 26.10, nor does it fulfill the NRC's original intent of section 26.27(b)(5). This revision would clearly recognize that instances of alcohol abuse pose a serious threat to safety and must be taken seriously.

Licensee Cost Reduction/Increase: This revision would be consistent with the current practice of most licensees. For the few licensees that would be affected by this revision, the costs of replacing or counseling and treatment (including follow-up testing) of violators are not expected to be significant.

Backfit Rule Considerations: Several commenters, including NEI, objected to the revision claiming, because the use of alcohol is legal, abusers needed "re-education" rather than sanctions. They also argued that licensees should determine the proper action rather than have the sanction required by the FFD rule. NEI's comment is spurious. The legality of alcohol use is not a relevant consideration. The FFD rule's purpose is to assure that licensee personnel performing safety functions are not impaired. It does not matter whether impairment is due to legal or illegal activities; the focus is the effect of those activities on the personnel and on safety. As noted above, a positive alcohol test is direct evidence of impairment that poses a serious threat to safety, whereas a positive drug test does not necessarily mean that there has been job impairment. NEI's position would impose harsher sanctions for a condition which is not necessarily an indicator of an immediate health and safety concern, while leaving unpunished a condition which directly indicates a health and safety concern, solely on the basis that alcohol is legal. Such an approach is arbitrary, in the Staff's view.

***Staff Conclusion:* This revision fits within the Backfit Rule's compliance exception.**

Section 26.28: Assure that appeal rights cover all types of violations, including confirmed positive test results from applicants for unescorted access and determinations of subversion

Revision: This revision would add applicants for unescorted access to those who have appeal rights under the FFD rule. In addition, it would provide appeal rights to all types of violations, rather than to positive test results.

Purpose: Section 26.28 currently requires licensees to establish a procedure that enables their "employees" to appeal "positive alcohol and drug determinations." In originally creating this requirement, the Commission considered applicants for unescorted access to be employees and that it did not need to state that such persons must be among the people who have the right to appeal FFD policy violations (see discussion in *Federal Register* at 54 FR 24489, June 7, 1989, "the focus of [this] rule is...not directed at an employment relationship"). The NRC staff is aware of instances where licensees have denied appeal rights under Section 26.28 to applicants for unescorted access because they are not "employees." This section would be revised to clarify the NRC's original intent that applicants for unescorted access must be provided with appeal rights. The NRC's intent is based on the recognition that when the Federal Government requires a program that could jeopardize any individual's career, appropriate due process safeguards must be provided.

The words "positive test result" would be replaced with "a violation of FFD policy," in order to clarify that all FFD policy violations, and not just positive test results, can be appealed. This change is one of a number of conforming changes where the term "positive test result" would be replaced with "a violation of FFD policy."

Licensee Cost Reduction/Increase: The Regulatory Analysis estimates that this revision will result in 56 additional applicants taking advantage of licensee FFD appeals processes annually among all 112 licensees subject to the rule. This will result in additional annual industry-wide costs of \$56,000.

Backfit Rule Considerations: The Commission explicitly expressed its intent in the original rule in section 26.28 that all persons subject to testing required by Part 26, including applicants, be afforded an opportunity to appeal positive alcohol or drug determinations and FFD policy violation determinations. This intent is shown by a NRC response to a public comment on the original proposed rule that stated that licensees' appeal procedures should be available to all employees covered by Part 26. (See NUREG-1354, Item 14.2.8, p. 14-8.) The FFD rule's current requirement in section 26.24(a)(1) that applicants for unescorted access be subject to pre-access drug and alcohol testing brings

these persons within the rule's coverage. The NRC staff is aware, however, that some licensees do not afford applicants the right to appeal violation determinations. This revision would bring those licensees into compliance.

NEI proposed a limitation to the clarification. NEI recommend that this section be further revised such that the right of appeal would apply only in cases when denial of unescorted access to a licensee, contractor, or vendor employee or an applicant for unescorted access would adversely affect that person's employment. In NEI's view, this revision would make the FFD appeal requirement consistent with that of the access authorization rule [10 CFR 73.56(e)]. NEI also requested that, unless the Commission places limits on the appeal rights, the proposed revisions should be addressed as backfits. In response to NEI's proposed limitation to the appeal rights, it is not clear how licensees could determine when denial of unescorted access because of an FFD policy violation would adversely affect people's future employment. In the NRC staff's view, all such denials would have an adverse effect. As the Commission noted when it published these proposed revisions, determinations of FFD policy violations can effectively bar workers from future employment in the nuclear industry. Licensees cannot be expected to know the future employment consequences outside the nuclear industry of a policy violation when determining whether an applicant should have a right to appeal that violation determination. The staff has reviewed both the FFD and access authorization rules and is satisfied that the appeals requirements have a consistent regulatory intent. FFD rule section 26.28 requires an appeals process to assure that any FFD policy violation determination is based upon correct facts. Section 26.27(a) requires applicants for unescorted access to submit a written statement that covers, among other things, whether they in the past five years have been determined to have violated an FFD policy. This requirement creates consequences for employment for at least five years following a violation. If there is any further violation or denial of access, the duration of consequences would be much longer. The access authorization rule's section 73.56(e) requires a review procedure to assure that the information that constitutes the grounds for denial or revocation is correct. Under section 73.56(b)(3) the licensee is required to consider all pertinent information developed. Under both rules, but with certain limits imposed by section 26.27(b), licensees may choose to retain a worker despite the development of adverse information, and receipt of future adverse information does not automatically affect employment.

***Staff Conclusion:* This revision fits within the Backfit Rule's compliance exception.**

Section 26.28: Assure that relevant records are corrected if appeal is successful

Revision: Section 26.28 would be revised to make it clear that, when an employee's appeal of a determination of an FFD policy violation is successful, the licensee must correct the relevant records.

Purpose: This clarification is consistent with the current requirements of section 26.24(d)(2) regarding the correction of records for individuals denied access based on a presumptive positive test for marijuana or cocaine that is subsequently not confirmed as a positive test result. This is also consistent with the NRC's assumption that all records, material in some respect to the NRC's mission, are complete and accurate as exemplified by 10 CFR 50.5(a)(2) and 50.9(a). It is also consistent with requirements in section 26.27(a) that require licensees to have records of the reasons for removal of unescorted access to respond to suitable inquiries and to retain records under section 26.27(c). These requirements are currently limited to records of violations. Under the current rule, an individual's records regarding the original violation, but not the record of the appeal, could be provided in response to a suitable inquiry. Given the seriousness for the individual if the records are not corrected after a successful appeal, this is an important revision that would implement the Commission's intent to protect individual rights consistent with its public health and safety responsibilities.

Licensee Cost Reduction/Increase: No cost impact.

Backfit Rule Considerations: The Commission explicitly expressed its intent in 10 CFR 50.5(a)(2) and 50.9(a) that all records that are material in some respect to the NRC and its licensees must be complete and accurate. The wording added to section 26.28 merely recognizes this long-standing and common-sense licensee responsibility to ensure that records are complete and accurate. This revision is necessary to ensure that all licensees and others implementing an FFD program under Part 26 that may not already be doing so will come into compliance with the NRC's requirements to maintain complete and accurate records.

***Staff Conclusion:* This revision fits within the Backfit Rule's compliance exception.**

Section 26.29(c): Assure provision of copies of records to individuals upon written request

Revision: Section 3.2 of Appendix A in the current rule would be moved to new section 26.29(c), and that language would be amended to clarify that "access to" records means the licensee shall promptly provide copies of such records. In addition, consistent with other revisions to the rule, the phrase "FFD policy violations, including test results, MRO reviews," would replace the term, "test results" in new section 26.29(c).

Purpose: Section 3.2 of Appendix A currently requires that licensees must provide to a subject employee, upon written request, access to all records pertaining to the employee's "tests." These records include test results, MRO reviews, and management determinations pertaining to the particular employee's violation. These revisions make clear the NRC's intent that people covered by the rule should have full and convenient access to documents pertaining to any employment actions taken in response to the rule such as determinations of subversion and other policy violations, not just those taken in response to "tests." The requirements would be moved from section 3.2 to section 26.29 would provide proper placement and emphasis.

The staff is aware that some licensees have interpreted the section 3.2 requirements in ways that make it difficult for employees to obtain their records. For example, there were several similar cases where the licensee informed a former worker who was now residing several hundred miles from the site that the records would be available for examination but that they would not provide copies. These interpretations run counter to the Commission's intent that people covered by the rule have full and convenient access to documents pertaining to FFD-related employment actions. The revision addresses Commission concerns on this matter expressed in an SRM dated March 27, 1991.

Licensee Cost Reduction/Increase: The Regulatory Analysis takes a conservative approach in assuming that all 112 licensees have not been providing their employees with copies of records pertaining to FFD policy violations to the extent that the NRC has intended. This leads to the estimate that the 112 licensees will each incur annual recurring costs of \$200 to comply with this rule revision, creating an industry-wide annual cost of approximately \$22,000.

Backfit Rule Considerations: The revision restates and clarifies the requirements of the current section 3.2 of Appendix A. NEI and another commenter recommended that the information regarding FFD policy violations should be limited to test results and summary information regarding the violation determination. NEI stated that in such circumstances employees need nothing but the facts that establish the policy violation and a statement

of events leading to the determination. The staff disagrees with NEI's approach that would place this limit on the records available to the individual. Retaining the requirement for provision of HHS-certified laboratory certification review or revocation, for example, continues the rule's consistency with the HHS Mandatory Guidelines (59 FR 29924; June 9, 1994). The staff regards such consistency as a desirable objective.

Staff Conclusion: This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule, in order to provide individuals with greater access to documents and information that may have an adverse effect on their careers due to NRC requirements. This revision is also consistent with the intent of the HHS Mandatory Guidelines.

Sections 2.4(g)(13) and (15) of Appendix A: More restrictive temperature range for an acceptable urine specimen

Revision: This revision would create a more restrictive temperature range for an acceptable urine specimen. The NRC rule's current acceptable temperature range is 32.5° – 37.7° C/90.5° – 99.8° F. Under the revision, the temperature range would be left up to each licensee to designate, but it would have to be within a band of 3° C/6° F or less, with a lower limit of not less than 34° C/94° F.

Purpose: Section 2.4(g) of Appendix A requires that licensees take certain precautions to assure that "authentic specimens are obtained." To this end, section 2.4(g)(13) currently specifies a temperature range that urine specimens must be within to meet this requirement and be acceptable for testing. This temperature range is one of the current minimum requirements designed to deter and detect subversion of the testing process. Experience has shown that the current temperature range is not adequate for achieving the original purpose of assuring authentic specimens. The rule's current acceptable temperature range is 32.5° – 37.7° C (90.5° – 99.8° F). With increased sophistication of methods of subverting the testing process, it has been discovered that it is relatively easy to provide a surrogate sample that is within this range using well known techniques (see NUREG/CR 6470, Chapter 6). For example, one individual was able to warm a surrogate specimen, contained in a fake bladder strapped to the inside of his thigh to 92° F by holding his legs together. Therefore, sections 2.4(g)(13) and (15) have been revised to narrow the current temperature band for acceptable urine specimens.

Under this revision, the temperature range will be left up to each licensee to designate. The temperature range would have to be within a band of 3° C/6° F or less, with a lower limit of not less than 34° C/94° F. Several licensees have adopted this proposed

standard and have realized significant improvement in detecting surrogate (non-authentic) samples. As discussed in Group IIB of this document, each licensee will be able to set its own temperature band to fit the particular urine temperature measuring device it uses. Since the FFD rule was published in 1989, there have been improvements in urine temperature measuring devices that now make use of a narrower temperature range feasible.

There are a number of acceptable options for recording temperature that allow different minimum and maximum acceptable readings under the revised specifications. Some suggested methods of adapting to the narrower temperature range include the use of peak temperature measuring devices, maintaining the ambient temperature in collection facilities at no less than 65 degrees Fahrenheit and measuring temperature of specimens within two minutes of voiding, or maintaining the ambient temperature in the collection facilities at no less than 70 degrees and measuring specimen temperature within three minutes of voiding, along with using a collection cup designed to resist effects of ambient temperature (e.g., a cup with little direct surface area in contact with ambient air and minimal inner surface area). If licensees decide to use such options, the NRC expects any associated additional costs would be minimal. This narrower range maintains the rule's anti-subversion measures by retaining a method of making attempts to submit surrogate samples more difficult.

Licensee Cost Reduction/Increase: There will be a few additional subversion attempts detected at each site during an initial implementation period. Once the workforce understands the difficulty in "beating" the new temperature standard, the number of attempts to submit surrogate samples will be significantly reduced. Therefore, there should be no significant cost impacts over the long term.

Backfit Rule Considerations: Section 2.4(g) of Appendix A currently requires licensees to take precautions to ensure that authentic urine specimens are collected and that measuring the specimen's temperature was important in determining if a specimen had been altered or substituted [see sections 2.4(g) and 2.4(g)(14) of the current rule]. Experience has shown that substance abusers have easily exploited the current temperature standard to avoid detection of surrogate samples. Therefore, this revision would modify a standard that is no longer achieving its intended purpose.

NEI recommended that the Commission establish 32° – 38° C/90° – 100° F as the acceptable temperature range. NEI favored this temperature range because it would be

consistent with other Federal standards including the HHS Mandatory Guidelines.⁴⁸ NEI also acknowledged that experience indicates that use of a more stringent temperature range is a sound practice that minimizes subversion. NEI suggested, therefore, that the Commission's proposed narrower temperature range should be considered a program goal rather than a mandated requirement. NEI also stated that the NRC's proposed narrower temperature range would increase the number of urine specimens that would be deemed of questionable validity and consequently require a significant number of employees to produce second specimens. The staff believes that the more restrictive temperature range is an important measure to continue to deter and detect the submission of surrogate samples and assure that specimens are authentic, as required by the original rule in section 2.4(g) of Appendix A. Licensees that have adopted the more restrictive temperature range have reported a dramatic increase in detection of surrogate specimens. NEI's concern about a "significant number" of employees having to produce a second specimen should not be realized. As described immediately below, improvements in temperature measurement and better control of ambient temperatures, better management of time between notification and collection and between collection and measurement of specimen temperature, and other measures will negate these potential problems. NEI's concern that more substance abuse would be detected is correct, but such detection is the purpose of the FFD program.

Staff Conclusion: This revision fits within the Backfit Rule's compliance exception.

Commission Determination: Upon reconsideration, the Commission has decided not to adopt a narrower temperature range as the Staff recommended. Insufficient data exists showing whether there would be a significant number of true positives identified using the more restricted temperature range that are currently classified as negatives. Thus, it is unclear whether the benefits of identifying these true positives outweighs the cost of additional confirmatory testing for eliminating false positives. The existing temperature range requirement, which is consistent with the HHS Guidelines, is therefore retained in the final FFD rule.

⁴⁸The acceptable temperature range originally specified by the HHS Mandatory Guidelines was 32.5°, 37.7°C/90.5°, 99.8°F, the same range currently required by the NRC rule. In 1994, HHS revised its temperature range to 32°, 38°C/90°, 100°F, the same range NEI now recommends, for "practical reasons related to the normal divisions indicated on various types of temperature measuring devices."

Section 2.4(i) of Appendix A: Laboratory must receive specimens within 48 hours of shipment

Revision: This revision would establish timeliness standards to prevent specimen degradation and would stipulate that laboratories must receive specimens within 48 hours and perform a screening test within 72 hours of shipment, except under unusual circumstances.

Purpose: Section 2.4(i) of Appendix A currently sets specific requirements regarding how licensee collection site personnel are to transfer collected specimens to their HHS-certified testing laboratory for testing. Section 2.7(c) of Appendix A establishes refrigerated storage and timeliness standards for specimens awaiting shipment and upon receipt at the laboratory to prevent specimen degradation. Experience and research data have shown these standards were not preventing specimen degradation, since: (1) the current requirement allows specimens to be unrefrigerated for a time period during which substantial degradation can occur; and (2) the current requirements do not specify a time limit for shipping and testing upon receipt of the specimens, which can also lead to specimen degradation. See 61 FR 21122; May 1996. Therefore, the current standard needs to be modified to reduce the length of time that a specimen is not chilled.

The revision that was proposed in May 1996 would have required licensees to send specimens as soon as reasonably possible but "in no case" would the time between specimen shipment and receipt of the specimen at the HHS-certified laboratory be allowed to exceed 48 hours, or the time between shipment and screening test at the HHS-certified laboratory be allowed to exceed 72 hours. This revision was intended to minimize false negative test results caused by specimen degradation. It responds to the fact that certain drug analytes are lost or significantly deteriorate when the specimen is not refrigerated.

In a comment listed as a potential backfit issue, NEI agreed with the need to avoid specimen degradation. It objected, however, to the specificity of this revision. NEI argued that this requirement would require licensees to create new time tracking systems to accommodate the new time limits. Since licensees and the laboratories already have "timeliness tracking" methods in place, there should be no new burdens in that regard, as NEI contends. In response to NEI's concerns, the staff has altered this revision to incorporate flexibility in these specimen shipment requirements. Rather than require that "in no case" can the time between specimen shipment and HHS-certified laboratory receipt of the specimen exceed 48 hours or the time between shipment and the screening test at the laboratory exceed 72 hours, this section will now allow an exception to these timing requirements when unusual circumstances occur. This change would preserve the

idea that specimens must be shipped and processed expeditiously. But it would also give licensees the flexibility they need to accommodate unusual circumstances that make it infeasible to meet these timing requirements. Other existing provisions in the rule require, essentially, that specimens be refrigerated when not in process (shipment and testing) and would minimize specimen degradation problems, should unusual circumstances occur. By reducing the possibility of false negative test results, this revision would also support the Commission's fundamental expectation that test results are accurate.

Licensee Cost Reduction/Increase: This revision would create only minimal impacts on licensees because most licensees currently use a courier or express service and would have no trouble meeting the new timeliness standards. For those licensees that would have to revise their shipping procedures, the staff estimates that five licensees would have to spend an extra \$1,200 annually and ten other licensees would have extra annual costs of \$10,700 due to this revision. The total industry annual increase in costs would, therefore, be an estimated \$113,000.

Backfit Rule Considerations: The Commission established timeliness standards in section 2.7 of Appendix A for refrigeration, testing, and reporting of results by the laboratory, to assure that specimens are not degraded. Since the rule was originally adopted, the staff has become aware of research (described above) that indicates that the rule's current requirements in section 2.7(c) of Appendix A regarding the timeliness of the chilling of specimens to prevent degradation were not performing as intended and need to be modified. That research found that certain drug analytes in urine specimens deteriorate if the specimens are not chilled and tested within 72 hours of the specimens being produced. Some licensees may be unaware of these research findings and may still be handling specimens in ways that can lead to specimen degradation. This revision will provide a practical way to respond to these research findings and to implement the rule's current requirements intended to prevent specimen degradation by revising current timeliness standards which were not achieving their intended purpose.

***Staff Conclusion:* This revision fits within the Backfit Rule's compliance exception.**

Section 2.7(d) of Appendix A: Specimens questionable for adulteration or dilution at licensees' testing facilities must be shipped to HHS-certified laboratory for testing

Revision: This revision would require licensees performing on-site testing to also perform validity testing on-site, and to ship all specimens of questionable validity to their HHS-certified laboratory for special processing. The change with respect to validity testing is a

conforming change to the addition of Section 26.24(d)(1) [see discussion above under Group IB]. The change with respect to shipment of specimens of questionable validity is a conforming change which supports the adoption of the HHS requirements set forth in section 2.7(e) of Appendix A [see discussion above under Group I, above].

Purpose: Section 2.7(d) of Appendix A currently requires licensees doing on-site testing to ship specimens determined to be presumptively positive to an HHS-certified laboratory for testing. New section 2.7(e) would require such licensees to determine on-site the validity of all specimens. A conforming revision to section 2.7(d) directs licensees doing on-site testing to ship to the HHS-certified laboratory those specimens it determines to be questionable because of adulteration or dilution. These measures are intended to ensure that licensees conducting on-site testing do not prematurely dispose of adulterated or diluted specimens.

Licensee Cost Reduction/Increase: The regulatory analysis estimates that this change would create no cost impacts independent of those discussed under section 2.7(e) below.

Backfit Rule Considerations: This revision would clarify how licensees are to comply with current requirements to take precautions against adulteration and dilution in sections 2.4(g) and 2.7(d). As noted in the discussion of the new section 2.7(e), the FFD rule has from its inception required licensees to take measures to assure specimen validity and prevent subversion of the testing process. The rule, however, did not specify how licensees were to achieve these aims. The new section 2.7(e) now provides specific requirements. The section 2.7(d) requirement under discussion here, that licensees send specimens of questionable validity to their HHS-certified laboratory for testing is, therefore, not a new requirement. It conforms with the clarification and guidance regarding existing requirements provided by the new section 2.7(e). Among other things, it will ensure that licensees do not prematurely dispose of specimens suspected of subversion. This revision will clarify current requirements.

***Staff Conclusion:* This revision is not a backfit because it clarifies, but does not change, a current requirement.**

Section 2.7(e) of Appendix A: Require on-site testers to determine validity of specimens on site

Revision: A proposed new section 2.7(e) of Appendix A would require the testing of all specimens to determine their validity and the special processing of those specimens found to be of questionable validity. The part of section 2.7(e) discussed here would require licensees who test on-site to determine the validity of all specimens by testing for creatinine, acidity/alkalinity (pH), and the presence of nitrites at their on-site testing facilities. A conforming change to Section 2.7(d), which explicitly requires licensees who test on-site to *ship* all specimens of questionable validity to an HHS-certified laboratory for special processing, is discussed immediately above.

Section 2.7(e) also contains provisions which are discussed elsewhere. One provision would require that specimens found to be of questionable validity require special processing at HHS-certified laboratories. This is discussed in Group IIA above. Another provision of section 2.7(e) requires the HHS-certified laboratory to test specimens to determine validity and to conduct special processing of specimens found to be of questionable validity. This is discussed in Group IB above.

Purpose: The testing for specimen validity which is proposed in new section 2.7(e) is intended to prevent subversion of the testing process by detecting specimen adulteration or dilution. A full explanation of the need to counter testing subversion and other information on the technical basis for this revision can be found in the discussion of another part of the proposed new section 2.7(e) in Group IB, above. Licensees that do screening tests on site (and now dispose of specimens screened as negative) must perform these specimen validity tests to prevent false negative test results and the disposal of specimens that may be invalid (section 2.7(e) requires licensees that do not conduct on-site testing to have their HHS-certified laboratories conduct the validity testing, as discussed in Group IB above).

Licensee Cost Reduction/Increase: The staff is aware that several licensees that conduct on-site testing are currently taking measures to determine specimen validity similar to those required by this revision. Nonetheless, the staff has taken a conservative approach to determining the cost impacts of this revision by assuming that all these licensees will have to implement the procedures mandated by this revision. Their cost increase would be an estimated \$1 per specimen (less than \$0.50 for a "dipstick" that can be used for analysis of the three test parameters plus the labor cost of doing the test) resulting in an approximate annual increase of \$2,100 per licensee. These ongoing costs are expected to be offset somewhat by reduced costs of specimen recollection, due to increased certainty with respect to specimen validity under the proposed revision.

Backfit Rule Considerations: The NRC's long-standing intent that licensees test specimens for validity to address subversion of the testing process is clearly stated in the FFD rule and in the statement of consideration for the current FFD Rule (54 FR 24494; June 7, 1989). For example, section 2.4(g) of Appendix A currently requires that "Licensees shall take precautions to ensure that a urine specimen is not adulterated or diluted...[and]...that authentic specimens are obtained...". Section 2.7(d) currently provides that "Special processing may be conducted to analyze specimens suspected of being adulterated or diluted (including hydration). Any evidence of adulteration or dilution, and any detected trace amounts of drugs or metabolites, must be reported to the Medical Review Officer." In the statement of considerations for the 1989 rule, the Commission noted that Appendix A to the rule contains "procedures for the collection of samples to ensure the integrity of the samples and limit opportunities for sample tampering." See 54 FR 24475. The requirements for validity testing and the special testing of questionable specimens in the proposed section 2.7(e) are specific means by which licensees can "take precautions" and conduct the kinds of "special processing" that are needed to ensure the integrity of the testing process. This revision would provide specific guidance, based on known methods for coping with subversion, for how licensees are to conduct special processing. This revision is an important component of specimen validity testing because the results will enable MROs to determine, in many cases, whether dilution was an attempt to subvert the testing process, or whether another specimen needs to be collected.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would enable MROs to determine, in many cases, whether dilution was an attempt to subvert the testing process, or whether another specimen needs to be collected. The revision would provide enhanced protection of public health and safety through improved capability of detecting substance abusers who are attempting to subvert the testing process. The costs of the testing would be offset somewhat by the need for fewer specimen recollections.**

B. Clarifications to existing requirements, changes to reduce interpretive debates, and administrative changes which are also proposed.

Section 26.2(a)(4): FFD program personnel to be covered by FFD rule

Revision: Section 26.2(a)(4) would be revised to clarify that FFD Program Personnel are to be covered by the NRC's FFD rule, and a new section 2.3(b) of Appendix A would be added to provide that FFD program personnel shall be tested by personnel independent of the administration of the FFD program to the extent practical..

Purpose: The current section 2.3 of Appendix A to Part 26 requires licensees to carefully select and monitor FFD program personnel based upon the highest standards for honesty and integrity. During the original rulemaking, the NRC assumed, incorrectly as it turned out, that these personnel would have unescorted access to the protected areas and, therefore, would be included in drug testing coverage by the broad application of section 26.2(a). Subsequent to the rule's effective date, several licensees have asked for staff guidance as to whether FFD program personnel should be subject to drug and alcohol testing. On numerous occasions over the past seven and one-half years, the staff has replied to these inquiries by stating that it was the Commission's intention (which the Commission approved in its SRM dated March 27, 1991) that FFD program personnel should be subject to testing. The staff has also stated this position in a number of public meetings over this period. The staff has pointed out in these instances that, if FFD program personnel are unfit due to drug or alcohol abuse, they will threaten FFD program integrity and acceptability to the workers being tested, and program operations generally.

Despite the Staff's guidance, there are a few licensees who do not test the appropriate FFD personnel. To assure that all licensees test the appropriate FFD personnel, section 26.2(a) would be revised to explicitly require that certain FFD program personnel are included within the rule's coverage and therefore subject to testing under the FFD Rule. These FFD program personnel would include people who can link test results with the employees tested, who make removal and return-to-work recommendations or decisions, or who are involved in the selection and notification of employees for testing or in the collection and on-site testing of specimens. FFD program managers, MROs, specimen collectors, employee assistance program (EAP) counselors, and other selected administrative staff are examples of FFD program personnel who would now explicitly be included under the rule's scope. This rule revision would help to insure the honesty and integrity of FFD program personnel who have an ongoing effect on safety. It would also increase management and work force confidence in FFD program integrity and the

reliability of test results. This revision addresses Commission concerns on this matter expressed in an SRM dated March 27, 1991.

Licensee Cost Reduction/Increase: This revision would likely result in some increased costs for the industry. It is the staff's understanding that virtually all licensees are now testing at least some of their FFD program personnel, particularly people who collect specimens and/or notify employees who are to be tested. Nonetheless, in the Regulatory Analysis prepared for this rulemaking, the staff estimates that two licensee FFD programs would add four people to their program coverage and thirty-seven licensee FFD programs would add two people. This would result in two programs (adding four people) incurring a one-time cost of an estimated \$1,100 for initial training and pre-access testing. The thirty-seven other programs (adding two people) would incur a one-time cost of an estimated \$400 for these purposes, resulting in a one-time industry-wide cost of \$17,000 for initial training and pre-access testing. These licensees would also incur additional expenses associated with a small increase in the number of random tests they conduct annually. The two FFD programs adding four people would incur an estimated additional \$280 annually and the thirty-seven programs adding two people would spend an additional \$140 annually for slightly expanded random testing. This total industry-wide annual cost would be an estimated \$6,000.

Backfit Rule Considerations: Section 2.3 of Appendix A states that licensees must carefully select and monitor FFD program personnel to ensure they meet the highest standards for honesty and integrity and that they implement measures to ensure that these standards are maintained. During the original FFD rulemaking, the staff believed that FFD program personnel would have unescorted access to licensees' protected areas and therefore be subject to testing which would support the provisions of section 2.3 for monitoring these people's honesty and integrity. Thus, the staff did not believe it to be necessary to explicitly include FFD program personnel within the rule's scope in the original rulemaking. This rulemaking would correct that error and explicitly require such testing of certain delineated FFD personnel.

Several commenters, including NEI, objected to this revision as one that would create an unnecessary burden. NEI stated that FFD program personnel who can link test results to people tested cannot affect test results and, therefore, cannot have an impact on FFD program effectiveness. NEI also argued that EAP personnel should not be included because, while they may recommend FFD actions to licensee management, they do not make the actual decisions about whether workers should be returned to Part 26 activities. A modification to this revision, in response to public comments, has been made to more clearly identify the specific FFD personnel to be covered by the rule, which would reduce

the coverage from that proposed in May 1996. This revision would specify that FFD personnel to be covered are those who are involved in the selection and notification of people to be tested, can link test results to tested employees prior to MRO determination of FFD policy violations, make management or medical determinations of fitness, and make removal and return-to-duty decisions. For example, EAP personnel who work off site, and who neither test individuals nor make removal or return-to-work decisions, would not be subject to the rule. This new revision would address most or all of the commenters' concerns about the originally proposed revision to this section.

Staff Conclusion: This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule. The revision would assure that FFD personnel, who perform an important safety function at nuclear power plants by virtue of their involvement in the implementation of the FFD program at licensees' facilities, are subject to the provisions of the FFD rule the same as other individuals that perform important safety functions at nuclear power plants. Requiring FFD personnel to be subject to the provisions of the FFD rule may also increase the perception by covered workers that the FFD testing process is fair and unbiased, and that the rule is applied equally across-the-board to all relevant workers.

Section 26.3: Revisions to Definitions: To support other rule changes, revise existing definitions, create new definitions, and relocate some definitions from Section 1.2 of Appendix A

Revision: This revision would revise existing definitions, create new definitions, and relocate some definitions from section 1.2 of Appendix A. Other definitional changes are either discussed elsewhere in this paper or make no changes of substance and, therefore, have no backfit implications.

Purpose: This section has been revised to clarify definitions of some terms, to make terms and definitions more consistent with those used by other Federal agencies (including the Substance Abuse and Mental Health Services Administration and the Department of Transportation), to provide new definitions to support other sections of the rule, and to remove three terms, "random test," "follow-up testing," and "suitable inquiry," because they are already adequately described in the text of the rule and do not need to be defined. In addition, several terms have been moved to this section from section 1.2 of Appendix A because they first appear in the main body of the rule.

New definitions have been provided for "abuse of legal drugs," "behavioral observation," "custody-and-control form," "history of substance abuse," "medical determination of fitness," "subversion," and "supervisor" to ensure clear and consistent understanding of terms used in Part 26.

The new definition of "medical determination of fitness" clarifies MROs' or other licensed physicians' roles in determining workers' fitness for duty and provides a standard for what properly constitutes this determination. It also makes clear that medical determinations of fitness are to be made by licensed physicians rather than medical personnel with lesser qualifications.

In response to public comments, several modifications have been made to the revisions proposed in the 1996 Federal Register Notice (FRN). The definition of "abuse of legal drugs" has been modified since the publication of the proposed rule revision to reflect changes recommended by public commenters. It now indicates that legal or employment actions stemming from the abuse of legal drugs are examples of evidence of the abuse of legal drugs rather than something that would constitute evidence of the existence of a health or safety hazard, as proposed in the SRM. The existing definition of "unconfirmed positive test" has been modified based on public comments to "presumptive positive screening test results." A new definition, "history of drug abuse," has been added in response to public comments. This definition clarifies the meaning of this term but makes no change to rule requirements. The existing definition of "confirmed positive test" has been revised to conform it to the meaning of related terms.

Licensee Cost Reduction/Increase: No cost impact.

Backfit Rule Considerations: The revisions to this section ensure clear and consistent understanding of terms used in the rule. They do not establish any requirements, but may be considered clarification of existing requirements. Commenters suggested a backfit analysis was warranted on some of the revisions to this section. NEI recommended the definition of "medical determination of fitness" be deleted or modified. It asserted that this new definition would create an unwarranted increase of MROs' duties and would involve them in administrative and management decisions and in the direct application of FFD policy for the licensee. NEI also proposed that any type of medical professional should be suitable for making medical determinations of fitness. NEI stated that this proposed change would create an increase in licensee burden and asked that it be justified as a backfit.

NEI also recommended against having the definition of "abuse of legal drugs" state that legal or employment actions stemming from the abuse of legal drugs should be deemed to automatically constitute evidence of a health or safety hazard without first having an MRO review the situation. NEI objected to the revised definition of "confirmed positive test" because it would not account for the situations in which MROs cannot verify laboratory confirmed positive tests as FFD policy violations because the tested employees are unavailable. If the NRC were to decide not to accept these latter two recommendations, NEI asked that these proposed definitional revisions be justified as backfits.

The proposed revision adds the definition of "medical determination of fitness" to clarify the rule to conform with the Commission's original expectation that MROs or other licensed physicians who are qualified (by virtue of education and /or experience) to make a medical determination of fitness are the appropriate people to conduct medical evaluations. Evidence of that intention can be found in the Commission's discussion of reinstatement of unescorted access in the Federal Register notice in which it proposed the original FFD rule (53 FR 36814 - 36817; Sept. 22, 1988). There the Commission made it clear that it considered the determination of a worker's fitness to return to duty to be an often very complicated and difficult decision. In several places, the NRC stressed the need for these decisions to be made by medical people who are clearly qualified in the analysis and treatment of substance abuse disorders which is the medical problem being presented. This is consistent with the position taken by HHS in section 2.6(b) of its Guidelines, which requires that the MRO be a licensed physician with knowledge of substance abuse disorders. HHS and NRC staff agree that anything less would jeopardize public health and safety and the rights of the individual. The NEI alternative, which would allow "any" medical professional to make these decisions without regard to their training and qualifications with respect to substance abuse, is clearly inconsistent with the Commission's intent.

The staff has decided to change the proposed new definition of "abuse of legal drugs" along the lines recommended by NEI. The new definition would indicate that legal or employment actions stemming from the abuse of legal drugs are presumptive of the abuse of legal drugs rather than something that would constitute evidence of the existence of a health or safety hazard. The staff also agrees with NEI's concern that the rule does not currently address situations in which MROs cannot verify laboratory confirmed positive tests as FFD policy violations because the tested employees are unavailable. Instead of proposing a revision to the definition of "confirmed positive test," however, the staff is recommending new wording in section 26.24(f) that would accomplish this purpose. These rule revisions would create no new burden for licensees.

Staff Conclusion: These revisions are not a backfit because they clarify, but do not change, current requirements.

Section 26.7: New section ensures communications are sent to Document Control Desk

Revision: A new section 26.7 would be created to notify licensees that all FFD communications and reports are to be sent to the NRC's Document Control.

Purpose: This revision is intended to ensure that communications with the Commission are processed properly.

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: This is an administrative change.

Staff Conclusion: This revision is not a backfit because it is an administrative change.

Section 26.8(c): Section regarding burden estimates deleted

Revision: This revision to section 26.8(c) would delete the section on estimating burden, as requested by the Chief, Information and Records Management Branch, OCIO.

Purpose: This section is no longer applicable.

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: This is an administrative change.

Staff Conclusion: This revision is not a backfit because it is an administrative change.

Section 26.20: Minor clarifying and conforming edits (Introduction, (c), (d), (e)(2))

Section 26.20(a): Off-site involvement with drugs, subversion of the testing process, and refusals to test added to policy statement

Section 26.20(a): Clear and concise policy statement must be readily available

Section 26.20(a): Policy must address impairment from legal drug use

Sections 26.20(d)(3) and (4): Policy must specify actions to be taken for subversion and refusal to provide a specimen

Revision: These revisions would require licensees' FFD policy statements to explicitly address off-site involvement with illegal drugs or the abuse of legal drugs, subversion of the testing process, and refusals to provide a specimen for testing. The revisions would require licensees to provide a short, concise summary of their FFD policy statement to personnel covered by the rule. The revisions would also make minor clarifying and conforming edits in the Introduction, and paragraphs (c), (d), and (e)(2).

Purpose: Section 26.20(a) currently requires that licensees create an overall description of their policy on fitness for duty that addresses several FFD concerns. Legal challenges have emphasized the need for all aspects of the FFD program, including sanctions, be stated clearly in the licensee's policy statement.

With respect to off-site involvement with illegal drugs (e.g., sale, distribution, use, or possession of illegal drugs, or the sale, distribution, use, or possession of legal drugs in a manner in violation of applicable laws), the original rule did not specifically require licensees' policies to address off-site involvement with drugs because it was assumed that licensees' existing personnel conduct policies covered such situations.

Unfortunately, some licensees have encountered been unable to take action against individuals involved with off-site involvement with illegal drugs because their policies did not cover such off-site involvement. The revision to section 26.20(a) would require the FFD policy to address individual's off-site involvement with drugs.

New sections 26.20(d)(3) and (d)(4) require that an employee's attempt to subvert the testing process or refusal to provide a specimen for testing be included in the section 26.20(d) list of proscribed activities that, when detected, require immediate and follow-on actions to be taken by the licensees. This revision is required to make section 26.20(d) conform with other provisions of the rule.

Section 26.20(a) requires that licensees have a written FFD policy, but does not explicitly require that a clear and concise statement of the policy be distributed to all affected individuals. However, the Edison Electric Institute's "EEI Guide to Effective Drug and Alcohol/Fitness for Duty Policy Development," which was recognized by the Commission in its August 4, 1986 (51 FR 27921), Policy Statement on FFD as the basic guidance being used by licensees to develop and implement FFD programs, discussed the need for licensees to develop "a clear definitive corporate policy statement" that "should be presented in writing" to all employees and the need for licensees to ensure that the employees were aware of that policy. However, during inspections the staff found that a few licensees had no "policy statement" that was readily available to individuals subject to the FFD policy, and that where FFD policies were incorporated into procedures, the procedures were not readily available to those individuals. Accordingly, section 26.20(a) would be revised to explicitly state the need for a clear and concise written statement of the FFD policy that is readily available to all persons subject to the policy.

Licensee Cost Reduction/Increase: Licensees would have to modify their current FFD policies and procedures to respond to several conforming revisions involving several rule sections in addition to 26.20. The Regulatory Analysis, in providing a consolidated estimate of all costs to modify policies and procedures to implement all rule changes, indicates that 74 licensee FFD programs would have an estimated one-time cost of \$2,000, for a one-time industry-wide cost of \$148,000, to make these policy and procedure modifications. (Note this is for all changes to policies and procedures required by these proposed changes.)

Backfit Rule Considerations: The Commission explicitly stated its intent in the current section 26.20 that licensees must establish and implement written policies and procedures designed to meet the general performance objectives set forth in section 26.10 and specific requirements set forth in Part 26. The Commission was also explicit in requiring that affected individuals be provided information of what is expected and the consequences that may result from lack of adherence to the policy. NRC staff's long-standing and often expressed position that licensees must provide a short, concise summary of their FFD policy statement to personnel covered by the rule. Proposed revisions to section 26.20(a) would assure licensees comply with the NRC's original intent on several minor matters which include off-site involvement with drugs, subversion of the testing process, impairment from legal drugs, and that licensees provide a short, concise summary of the licensee's fitness-for-duty policy statement. The proposed new sections 26.20(d)(3) and (d)(4) assure conformance of the written policy with other provisions of the rule.

In Niagra Mohawk Power Corporation v. IBEW (1998 WL 227981) the U.S. Court of Appeals for the Second Circuit determined that there was no clear public policy on adulteration or dilution of specimens despite “the level of public concern over the safety of the nuclear power industry.” Therefore, an employee in a safety sensitive position who adulterated his specimen, whose second specimen was positive for cocaine, and who secreted vials of adulterants and clean urine in his locker should not have been terminated and must be returned to duty.

Staff Conclusion: The revisions with respect to the need for a concise written policy FFD policy fits within the Backfit Rule's compliance exception. The changes with respect to sanctions for subversion or refusing to provide a specimen are conforming changes and need not be analyzed separately from the primary change. Finally, the change requiring FFD policies to address offsite involvement of drugs is a worthwhile revision which the staff recommends be promulgated as an exception to the Backfit Rule to assure that licensees can take appropriate action against individuals who are identified as being involved off-site with illegal drugs.

Section 26.20(e)(1): Declaration of fitness to perform tasks assigned when contacted for call-in

Revision: This revision would have clarified that employees should report fitness status when called, not after arriving at the site.

Purpose: Section 26.20(e)(1) currently requires licensees to obtain a statement from people called in to perform an unscheduled working tour as to whether they have consumed alcohol within the length of time stated in the pre-duty abstinence policy. This revision would have required licensees to obtain these statements when the people are initially contacted on the telephone, as opposed to obtaining this statement when the people report for work. It would also require licensees to obtain a statement as to whether the called-in people consider themselves fit to perform their assigned tasks. This revision's purpose is to explicitly recognize, consistent with the current section 26.20(a), that there are factors beyond alcohol consumption, such as fatigue, illness, and use of medications, that licensees should be aware of before they ask employees to report for unscheduled working tours. It responds, in part, to cases in which licensees have penalized individuals for declining to come in because they did not believe themselves fit to perform duties. In addition, these revisions would afford employees an added safeguard in that they would have an opportunity to express their own opinion as to whether they believe themselves fit in view of fatigue, illness, use of medications or consumption of alcohol to perform assigned tasks. This requirement would also enable licensees to obtain the information over the telephone to avoid having to get that person

safely home after arriving on site unfit to work, call in another person, and avoid the potential for civil law suits that could arise from accidents while the called-in person is in travel.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: NEI objected to this revision because, in NEI's view, it would over regulate both licensees and their employees by requiring employees to make an extra statement that is not now required when employees report to work under routine circumstances. NEI argued that, while it might be appropriate for licensee FFD policies to require called-in employees to state whether they consider themselves fit to perform assigned tasks, the NRC should not require such statement by regulation. After further consideration, the staff believes that it is sufficient to obtain a statement from called-in employees at the time that they present themselves for duty, and the timing of the statement should be left to the licensees. Therefore, the proposed revision has been withdrawn.

Staff Conclusion: Not applicable.

Section 26.20(f): Statement regarding Commission's right to review licensee policy is deleted

Revision: This revision would remove the statement that the Commission may review the licensee's FFD policy and procedures at any time.

Purpose: This provision is unnecessary because the Commission's inspection needs are adequately covered in section 26.70.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: This makes no substantive change to the requirements of the rule and is an administrative change.

Staff Conclusion: This revision is not a backfit because it is an administrative change.

Section 26.21(a): Minor administrative and clarifying edits

Revision: Minor revisions to section 26.21(a) would change "shall" to "must" and the phrase "abuse of drug and abuse of alcohol" to "the use of illegal drugs and the abuse of legal drugs, including alcohol".

Purpose: This change clarifies the distinction between legal and illegal drug provisions.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: This is a minor clarifying edit.

Staff Conclusion: This revision is not a backfit because it clarifies, but does not change, a current requirement.

Section 26.22(c): Supervisory training for licensee employees must be completed as soon as feasible following assignment to supervisory duty

Section 26.22(c): Supervisory training for contractor employees must be completed no later than 10 days following assignment to supervisory duty

Revision: The current supervisory training requirements in section 26.22(c) would be revised in two ways. One revision would clarify the NRC's intent that escorts and supervisors employed by licensees receiving their initial supervisory assignments must complete their initial training in their FFD program implementation duties as soon as feasible. As this rule currently allows, however, these escorts and supervisors will still have up to three months to complete this initial training. The other revision would require supervisors employed by contractors who are receiving their initial supervisory assignment to complete their initial training in their FFD program implementation duties within ten days after that assignment instead of the three months currently permitted.

Another revision to this section, which would allow licensees the flexibility to use a written examination of supervisors and escorts employed by licensees on pertinent FFD issues in lieu of refresher training in two out of every three years, is discussed under Group IIB, above.

Purpose: Section 26.22(c) currently states that initial training of supervisors must be completed prior to assignment of duties and within 3 months after initial supervisory assignment. These revisions would clarify the rule's supervisory training requirements in

order to assure compliance. While it is not the intent of this section to hold up licensee supervisors' assumption of their duties, it is important that they receive their FFD training either before they do so or as soon as feasible thereafter.

The second revision, by contrast, would require that supervisors employed by contractors be trained within 10 days of assuming their duties. The stricter requirement for contractor supervisors, as opposed to licensee supervisors, is based upon data reported by licensees that show contractor personnel have had higher rates of positive test results relative to licensee employees. Therefore, it is particularly important that contractor supervisors complete their training either before or very soon after they assume their supervisory duties. The second revision would also prevent abuses, such as rotating contractor supervisors within the currently allowed three-month period, that have resulted in contractor personnel being supervised for long periods by people who have not been trained in FFD program requirements.

Licensee Cost Reduction/Increase: There would be no cost impact with respect to supervisors and escorts employed by licensees, since the revision simply clarifies the existing requirement. There would be no cost impact with respect to supervisors employed by contractors, since the revised requirement only affects the timing, but not the content, of the required training. Changing the timing of the training should not result in any increased costs to the licensee or (indirectly) to its contractors

Backfit Rule Considerations: The Commission explicitly stated its intent in the current section 26.22(c) that initial training of supervisors must be completed prior to assignment of duties and within 3 months after initial supervisory assignment. The three-month flexibility in completing the training for supervisors was originally created to allow people who have been promoted to supervisor to work in that capacity as soon as possible and to provide licensees with adequate time to accomplish the training and not delay the appointment. The staff is aware, however, that some contractors have used this flexibility to avoid training requirements by appointing workers for short-term (i.e., less than three months) supervisory assignments, after which they are replaced. As a result, these "3-month" supervisors are never trained in behavioral observation and other FFD program responsibilities even though contractor employees are responsible for the majority of FFD violations reported by licensees. In light of this experience, these revisions would tailor the training requirements to distinguish between licensee and contractor supervisors so as to meet the Commission's original expectations as to what should be considered a reasonable period in which to complete FFD program training.

NEI recommended treating the FFD training of all supervisors the same way rather than distinguishing between supervisors of licensee employees and contractor supervisors in setting training requirements because it would create an unnecessary tracking burden. A contractor/vendor commented that the proposed revision would discriminate against contractors. As discussed above, because contractor personnel have consistently had higher positive test rates and because some contractors have abused the three-month flexibility granted by this section so that contractor supervisors are not trained, the staff believes that this section should distinguish between supervisors employed by licensees and supervisors employed by contractors.

The Department of Nuclear Safety, State of Illinois, was concerned that, in some cases, 10 days might not be sufficient time to provide training to new department supervisors. The NRC continues to believe that the 10 day period is reasonable and, considering the large number of contractors that are affected, the timeliness standard should not be relaxed for an isolated possibility. Should such an event occur, the Department should document the reason for the delay in the supervisor's training file.

***Staff Conclusion:* The revision with respect to supervisors and escorts employed by licensees is not a backfit because it clarifies but does not change, a current requirement. The revision with respect to supervisors employed by contractors fits within the Backfit Rule's compliance exception.**

Section 26.23(a)(2): Clarify that persons with a known (to the contractor or vendor) history of substance abuse must not receive assignments to the protected area without the knowledge and consent of the licensee

Revision: Section 26.22(a)(3) would be revised to state that contractors and vendors are to inform licensees of any known substance abuse history of persons assigned to the protected area.

Purpose: Section 26.23(a)(2) currently forbids contractors and vendors from assigning personnel who have previously been denied access or removed from work due to FFD policy violations to work within the scope of Part 26 without the knowledge and consent of the licensee. However, the regulation does not require contractors and vendors to inform and obtain the consent of licensees when assigning personnel "with a known history of substance abuse." This revision would require contractors to inform and obtain the consent of licensees when contractors are contemplating assigning people who have a history of substance abuse, since such a history may raise current FFD concerns for those individuals. It provides a clear legal basis for prosecution by the Department of

Justice should a contractor or vendor deliberately withhold such information from a licensee, which has happened on a few occasions. In those cases, the contractor was aware of a history of substance abuse not involving a removal by an NRC licensee and withheld that information.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: This revision has a minimal cost impact, since contractors are already required to report to licensees information regarding known denials of access and removals.

NEI objected to adding “with a known history of substance abuse” because it was redundant to the current requirements in section 26.23(a)(2) pertaining to persons denied access or removed for violating an FFD policy. However, redundancy is not a backfit issue. More importantly, NEI’s argument is incorrect because there is nothing in the current regulation which explicitly addresses the vendor’s or contractor’s responsibility to report to the licensee information regarding a “known history of substance abuse” for its employees.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it ensures that licensees have all relevant information in determining whether an individual, because of his past substance abuse history, should be granted unescorted access.**

Section 26.24(a)(1) and (a)(2): Specify that all testing prior to granting unescorted access is to be called pre-access testing and that randomly scheduled testing is to be called random testing

Revision: Section 26.24(a)(1) would be revised to provide the term "pre-access testing" to be applied to the testing required by this section. Likewise, section 26.24(a)(2) would be revised to provide the term "random testing" to be applied to the testing required by that section.

Purpose: Although section 26.24(a) has always required pre-access and random testing, the names "pre-access" and "random" do not now appear in this section. These revisions would add these designations to the section but make no change of substance to this section.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: By providing names for two existing types of required testing, this revision would make an administrative change to the rule.

Staff Conclusion: This revision is not subject to backfit requirements because it is an administrative change.

Section 26.24(a)(1): Clarify that negative pre-access test result must be obtained prior to access

Revision: Section 26.24(a)(1) would be revised to clarify the requirement that, before granting a person access following a pre-access test, the licensee must obtain a negative test result.

Purpose: Although section 26.27(b) currently requires that a person be removed from unescorted access as a result of a positive test result, section 26.24(a)(1) does not explicitly state the Commission's intention that negative test results be obtained before access is granted. Most, if not all, licensees have always refrained from granting access before receiving a negative test result on a pre-access test. Granting access before receiving a negative test result would negate much of the utility of conducting the testing in the first place. This clarifying revision would make this requirement explicit.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: NRC guidance on FFD Rule implementation issued at the time the rule was promulgated in 1989 states that negative pre-access test results must be obtained before unescorted access is granted (see item 4.5 of NUREG-1385). Failure to obtain a negative result before granting access would negate the underlying purpose of pre-access testing. This revision would assure compliance with the Commission's intent when promulgating the pre-access testing requirement.

Staff Conclusion: This revision fits within the Backfit Rule's compliance exception.

Section 26.24(a)(2): Random testing must be conducted on weekends, backshifts, and holidays

Revision: Section 26.24(a)(2) would be revised to make it clear that random testing must be conducted on weekends, backshifts, and holidays so that random testing procedures permit no "safe periods" for any employee.

Purpose: This revision would clarify the meaning of random and unannounced testing. Most licensees randomly select about 5 percent of those periods per year, and randomly test those on duty during those reduced manning periods. This revision will clarify that practice.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: The Commission explicitly stated its intent in the current section 26.24(a)(2) that the timing of random testing must be unpredictable and that such testing must be conducted at various times during the day and that all persons have an equal probability of being selected and tested. In item 4.6 of NUREG-1385, the NRC, in expressing its intent, quoted HHS's "Medical Review Officers Manual": "Each work day should present each employee with a new opportunity of having to produce a sample...". Therefore, it has always been the NRC's intent that random testing must be conducted on weekends, backshifts, and holidays to meet this section's "unpredictable" and "various times" requirements. Allegations and inspections have disclosed that licensees have not always complied with this intent. Therefore, this revision is necessary to bring these licensees into compliance with current rule requirements.

***Staff Conclusion:* This revision fits within the Backfit Rule's compliance exception.**

Section 26.24(a)(2): Individuals selected for random testing during an absence of 60 days or more to be tested only once to meet both random and return-to-duty testing requirements [see section 26.24(a)(5)]; tests to be reported as random

Revision: This revision would clarify that individuals selected for random testing during an absence of 60 days or more are to be tested only once to meet both random and return-to-duty testing requirements. Such tests are to be reported as a random test for statistical purposes. This is a companion change to the revision to section 26.24(a)(5) requiring return-to-duty testing after extended absences, discussed in Group IIIA.

Purpose: Currently, section 26.24(a)(2) requires random testing, but there is no requirement for return-to-duty testing after extended absences. New section 26.24(a)(5)

would require return-to-duty testing after extended absences. Without the revision to section 26.24(a)(2) discussed here, employees who have been selected for random testing during an absence of more than 60 days, who would also need to have a return-to-duty test under section 26.24(a)(5). The revision to section 26.24(a)(2) would provide that only one test need be given, and that it be treated as a random test for statistical purposes.

Licensee Cost Reduction/Increase: There is some indeterminate savings resulting from prevention of duplicate testing.

Backfit Rule Considerations: This revision is intended to prevent duplicate testing in meeting the random and the new return-to-duty testing requirements in section 26.24(a)(5).

Staff Conclusion: This revision is not a backfit because it provides a relaxation of a proposed new requirement in section 26.24(a)(5) in Group IIIA above (the backfit implications of the new section are discussed separately there).

Section 26.24(a)(3): Clarify conditions that initiate for-cause test

Revision: Section 26.24(a)(3) would be revised to clarify for-cause testing provisions by making two minor edits: "physical condition" has been added to "observed behavior" and "individual's performance" replaces "worker's behavior." Another revision would have made clear that attempts to subvert the testing process are an indication of substance abuse that should trigger for-cause testing.

Purpose: Section 26.24(a)(3) currently directs licensees to test their employees for cause under certain specified circumstances. These circumstances include when an individual's behavior indicates possible substance abuse or contributes to an accident. Two minor editorial changes have been made to this section. One states that a worker's physical condition, as well as his or her behavior, may be an indication of a need for-cause testing. The other editorial change specifies that the worker's "performance," rather than his or her "behavior," should trigger for-cause testing. These minimal changes have been made for purposes of clarifying long-standing for-cause testing criteria.

Another change to this section, the addition of "including attempts to subvert the testing process," has been withdrawn based on public comment that section 2.4(g)(17) of Appendix A currently requires collection of a second specimen as soon as possible under

direct observation whenever there is reason to believe (a for-cause situation) that a person to be tested may alter or substitute the urine specimen to be provided.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: These revisions are minor editorial changes that clarify existing requirements and create no new licensee burden.

***Staff Conclusion:* This revision is not a backfit because it clarifies, but does not change, a current requirement.**

Section 26.24(a)(3): Ensure removal of unfit persons and determination of fitness prior to return to duty

Revision: Section 26.24(a)(3) would be revised by adding a new subparagraph (ii) which specifies that, for an individual who is administered a for-cause test, the individual's unescorted access status must be suspended until the individual has been pronounced fit for duty based on a management and medical determination of fitness.

Purpose: Section 26.24(a)(3) currently requires licensees to subject workers to for-cause testing when certain conditions stated in the section indicate the need for such testing. This revision reiterates the long-standing requirement stated in 26.27(b) that "Impaired workers or those whose fitness may be questionable shall be removed from activities within the scope of this part, and may be returned only after determined to be fit to safely and competently perform activities within the scope of this part". Despite the rule's current wording, the staff is aware that several licensees have failed to take prompt action when the fitness of a manager or licensed operator was questionable and that at least one licensee has returned a licensed operator to duty without having effectively evaluated his fitness. Since licensees are not required to report these types of events concerning the general workforce, the staff has no specific information on the total number of these events. Therefore, revisions to this section and to section 26.27(b) will ensure that such return-to-duty decisions are made by an appropriate manager and a licensed physician qualified to make a medical determination of fitness.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: The Commission explicitly stated its intent in the current section 26.27(b) that licensees must remove employees whose fitness may be questionable from Part 26 activities and return them to duty only when they have been

determined to be fit to safely and competently perform activities within the scope of Part 26. However, licensees have not always complied with these requirements. Therefore, this revision is needed to emphasize the relationship between section 26.24(a)(3) and 26.27(b), and to assure compliance with the requirement to remove unfit persons and return them to duty only when fit.

Staff Conclusion: This revision fits within the Backfit Rule's compliance exception.

Commission Determination: After consideration of the public comments, the Commission has decided not to adopt the Staff's recommendation for a requirement that a medical determination of fitness be performed to evaluate employees who test negative in a for-cause test. In situations such as preaccess and return-to-duty testing, the fitness determination is ordinarily made during normal work hours when the MRO is on-duty. By contrast, the need for a medical determination after a negative for-cause test could occur during off-normal work hours when the MRO is not available. In this situation, the licensee would have the following options: (1) provide an MRO on a 24-hour or as-needed basis or (2) defer the medical determination until normal work hours. The added costs and reduced flexibility would only occur in negative for-cause tests, and there is insufficient data to show that such costs would be justified in terms of the identification of significant numbers of unfit workers would only be identified as unfit by the MRO. Therefore, the Commission has decided that a medical determination after a negative for-cause test is not warranted.

Section 26.24(a)(4): Relocate follow-up testing requirements from section 26.27(b)(4/5) and clarify testing is to be unpredictable and tailored to medical history

Revision: This revision would clarify follow-up testing requirements.

Purpose: Section 26.27(b)(4) currently requires follow-up testing for employees whose unescorted access is reinstated after a suspension under section 26.27(b)(3). This unannounced (and unpredictable) testing must be conducted no less frequently than once every month for four months and at least once every three months for the remainder of a three-year period. This revision would move this existing requirement from its current location in section 26.27(b)(4) to a more appropriate location in section 26.24(a)(4). A clarification would also be made to ensure that follow-up testing properly addresses unusual situations by requiring the testing be tailored to the individual's medical history, but not less frequently than once every 30 days for four months after unescorted access is reinstated and at least once every 90 days for the next two years and eight months. This revision addresses Commission concern on providing more explicit testing

requirements following a positive drug test as expressed in an SRM dated March 27, 1991.

It should also be noted that the current requirement, that people to whom unescorted access is reinstated after suspensions must be subject to follow-up testing for a minimum of three years, is well supported by the research literature. That research indicates that chronic abusers of alcohol and other drugs usually need several years to recover from their habits. This revision will serve to reposition and clarify an existing requirement that continues to recognize the heightened chances for recidivism during the first three years after drug abuse is detected.

Since the specific criteria for follow-up testing was incorrectly placed in the current section 26.27(b)(4) instead of section 26.24(a)(4), some licensees interpreted that positioning in the rule to mean that follow-up testing was required only if a person had been removed for a period of three years or more (i.e. had a second positive test result). This revision will correct that misperception.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: This revision creates no new burden on licensees. Instead, it relocates a current requirement to a more appropriate rule section and clarifies the original intent of the rule--a person being returned to work must demonstrate the ability to abstain from substance abuse and be fit for duty. The revision changes the location of the regulatory requirement, provides a minor clarification, and does not impose any new requirement on licensees.

NEI suggested, under their listing of backfit issues, that the NRC reduce the frequency and duration of the rule's follow-up testing. Instead of raising any backfitting issues related to the proposed revision, NEI proposed its own new change to current requirements. In addition, NEI objected to the relocation of the follow-up testing requirements, asserting that this change would create a new requirement that would increase licensee burden. In response, the NRC staff believes that this proposed revision reflects the Commission's original intent that persons being returned to duty must demonstrate their ability to abstain from substance abuse and they must be subjected to follow-up testing to assure continued compliance with the licensee's FFD policy. Section 26.24(a)(4) already requires follow-up testing to verify continued abstinence from prohibited substances. Evidence of the NRC's intent in this regard can also be found in item 12.6.3 of NUREG-1354. In responding to public comments on its originally proposed follow-up testing requirement in that document, the Commission said in various contexts

that it expected that follow-up testing would be administered following confirmed positive test results for those being returned to duty. The Commission did not there or elsewhere restrict this requirement to only those instances where an employee has a second or third confirmed positive result. The relocation of the specific follow-up testing criteria from section 26.27(b)(4) to section 26.24(a)(4) is an administrative change.

Staff Conclusion: This revision is not a backfit because: (a) it clarifies, but does not change, an existing requirement, and (b) it is an administrative change.

Sections 26.24(a)(4), (c), (d), (f), (g), and (h): Minor clarifying edits

Revision: Minor edits.

Purpose: Make language of rule clearer.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: These changes are minor edits that make no substantive change.

Staff Conclusion: These revisions are not backfits because they clarify, but do not change, existing requirements.

Section 26.24(h): Clarify that blood testing for alcohol is for purposes of appeal

Revision: This revision would change wording in Section 26.24(h) [currently 26.24(g)] to clarify that blood testing for alcohol is not required for the confirmation of a positive test for alcohol.

Purpose: Section 26.24(g) currently provides for a gas chromatography analysis of blood to be administered if the tested person demands "further confirmation" of a positive confirmatory test result from breath alcohol analysis devices. This regulatory language would be revised to better reflect the originally intended purpose of blood tests. The new wording would stipulate that employees can choose to have blood tests performed to provide additional information that can be considered during an appeal pursuant to section 26.28. It would eliminate any confusion about whether a blood test is necessary to confirm a positive alcohol test result.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: This would be a clarification of the existing requirements.

Staff Conclusion: This revision is not a backfit because it clarifies, but does not change, a current requirement.

Section 26.24(h): Clarify that any detectable quantity of alcohol in a blood specimen may be considered to determine FFD violation

Revision: Section 26.24(h) (currently section 26.24(g)) would be revised to state that, when blood tests are administered for purposes of providing additional information for appeals of alcohol violations, any alcohol in the blood specimen may be considered together with the elapsed time between the confirmatory test and the test of the blood specimen in the appeal decision.

Purpose: Currently, section 26.24(g) contains no criterion for assessing the results of a test of blood administered at the subject individual's request for the purpose of assisting that individual's appeal of alcohol violations. This revision would provide that such a test, if confirming the presence of alcohol, could be considered in an appeal pursuant to section 26.28. A "cut-off level" criterion was not deemed to be acceptable, given the potential lengthy delay of time between the initial breath test and the collection of the blood specimen upon the individual's request. This revision would be consistent with HHS's policy on retesting of urine specimens for drugs, which appears in the current section 2.7(j) of Appendix A.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: This new wording would not create any new requirement for licensees. Instead, it would recognize and clarify a long-standing specimen retesting confirmation criterion, currently described in section 2.7(j) of Appendix A.

Staff Conclusion: This revision is not a backfit because it does not constitute a requirement imposed on the licensee. The provision on retesting of blood specimens is also consistent with the HHS Mandatory Guidelines on retesting of urine specimens.

Section 26.25: Clarify that EAPs must be designed to achieve early intervention and must assure confidentiality

Revision: Section 26.25 currently states that licensees' employee assistance programs (EAPs) "should be designed to achieve early intervention and provide for confidential assistance." This revision would replace the permissive "should" with the mandatory "must" to clarify the NRC's original intent that, in designing their employee assistance programs, licensees must have the program goal of achieving early intervention in all situations where employees' problems could adversely affect job performance. This revision would also clarify that EAPs must provide assistance to employees on a confidential basis in most situations.

Purpose: It was the NRC's original intent that licensees design and operate their employee assistance programs in such a way as to achieve early intervention in situations where employees' problems could adversely affect on-the-job performance and to provide their employees with confidential assistance in these circumstances. As originally worded, section 26.25 required that licensees "should" achieve these goals. This permissive wording was used to convey the idea that, while these goals may not be achievable in all situations, it would be reasonable to expect that the EAP programs would be designed to achieve these goals. While most licensees have, in fact, designed and operated their programs to achieve early intervention, a relatively few have not and have created "disincentives" to achieving the EAP goals. For example, some licensees treated employee self-referral to the EAP as the equivalent of a confirmed positive drug test and exacted sanctions accordingly. Treating employees' use of EAP services in this manner discourages employees from using the EAP to deal with fitness problems that could adversely affect their work performance and safety.

Licensee Cost Reduction/Increase: There are indeterminate cost impacts associated with this revision.

Backfit Rule Considerations: The Commission explicitly stated its intent in the current section 26.25 that employee assistance programs be designed to achieve early intervention and assure confidentiality. In its 1988 Federal Register notice publishing the then proposed FFD rule for public comment, the Commission stated that section 26.25 "requires licensees to maintain an EAP designed to achieve early intervention and to encourage self-referral" (53 FR 36818). In item 8.1 of NUREG-1385, the Commission stated that the EAP must not notify licensee management when a person seeks help through the EAP to solve a substance abuse problem unless the EAP medical personnel determine that the person constitutes a hazard to himself or to others. These two explicit

statements further demonstrate the Commission's original intent that licensees design their EAPs with the goal of achieving early intervention and that they must maintain confidentiality to encourage employees' self-referrals when an employee needs EAP services. While most licensees have designed and operated their EAPs accordingly, some have failed in one or both respects. Therefore, this revision is needed to ensure that those licensees comply with the NRC's original intent.

Staff Conclusion: This is a worthwhile revision that the staff recommends be adopted as an exception to the Backfit Rule. The proposed revision would ensure that all licensees seek to address substance abuse problems at an early stage, where the likelihood of success in addressing substance abuse is perceived to be highest.

Sections 26.27(a) and (b): Clarifying and conforming edits

Revision: These revisions would make minor clarifying and conforming edits beyond the changes to these sections discussed under Groups IA and IIB above, and IIIB, below.

Purpose: To make the language consistent with other changes to the rule.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: These would be minor edits.

Staff Conclusion: These revisions are not backfits because they clarify, but do not change, existing requirements.

Sections 26.27(b)(1), (3), and (5): Clarification of requirements with respect to access denial, removal, and return to service

Revision: Section 26.27(b)(1) would be revised to require that return-to-duty decisions are to be made by an appropriate manager and a licensed physician qualified to make a medical determination of fitness. Redesignated sections 26.27(b)(3) and (b)(5) [section 26.27(b)(2) and (b)(4) in the current rule] would be revised to require that return-to-duty decisions are to be made by an appropriate manager and a licensed physician qualified to make a medical determination of fitness, and that return-to-duty test under new section 26.24(a)(5) be conducted. Redesignated section 26.27(b)(3) would be revised to require that follow-up testing under revised section 26.24(a)(4) be conducted.

Purpose: Section 26.27(b)(1) currently requires licensees to remove workers who are impaired or whose fitness may be questionable from activities within the scope of Part 26, and that such people are not to be returned to their duties until they are determined to be "fit to safely and competently perform their duties." However, it does not specifically require that such determinations be accomplished by a licensed physician qualified to make a medical determination of fitness. The proposed revision would explicitly require that the determination be made by a licensed physician qualified to make that determination.

Similarly, sections 26.27(b)(2) and (4) [sections 26.27(b)(3) and (5) in the revised rule] currently require management and medical assurance of fitness before individuals who tested positive or were previously removed, but do not specifically require that such determinations be accomplished by a licensed physician qualified to make a medical determination of fitness. The proposed revisions would explicitly require that the determination be made by a licensed physician qualified to make that determination.

The redesignated sections 26.27(b)(3) and (5) would also be revised to make conforming changes with respect to return-to-duty tests under section 26.24(a)(5) (discussed above in section 26.24(a)(5) under Group IIIA) and that follow-up testing be conducted for a minimum specified period and frequency under section 26.24(a)(4) to verify the continued abstinence from the use of substances (discussed above in section 26.24(a)(4) under Group IIIB).

Licensee Cost Reduction/Increase: There may be some additional costs associated with the need to have a physician determination under section 26.27(b)(1), but there would be no additional costs associated with the need to have a physician determination under sections 26.27(b)(3) and (5), since this aspect of the change is a clarification of the existing requirement for a "medical assurance of fitness" ("medical" assurance can only be reasonably provided by a licensed physician qualified to make the appropriate determination). The costs associated with return-to-duty testing and follow-up testing are already accounted for in the primary discussion of these sections.

Backfit Rule Considerations: The staff is aware that several licensees have failed to take prompt action when the fitness of a manager or licensed operator was questionable and that, on at least one occasion, a licensee has returned a licensed operator to Part 26 duties without first effectively evaluating his fitness. Since licensees are not required to report these types of events concerning the general workforce, the staff has no specific information on the total number of these events. Therefore, revisions to these three sections are deemed to be needed to ensure that such return-to-duty decisions are to be

made by an appropriate manager and a licensed physician qualified to make a medical determination of fitness. These revisions also ensure that people are allowed to return to duty only after professionals qualified in work requirements and drug and alcohol abuse and fitness issues have had the chance to give these decisions the careful consideration they deserve.

NEI recommended deletion of the requirement that these decisions must be made by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. NEI asserted that this revision would go beyond setting a standard for compliance by telling licensees how to actually comply with the standard. In NEI's view, this goes beyond the Commission's proper regulatory role. The staff disagrees. These revisions clarify the meaning of and assure compliance with the current requirement of a management and medical assurance of fitness before previously impaired workers or workers who have violated an FFD policy are allowed to return to duty. They also reflect the Commission's original intent that FFD policy violators be subject to return-to-duty and follow-up testing to assure continued compliance with the licensee's FFD policy. Evidence of the NRC's intent in this regard can be found in sections 26.24(a)(4) and 26.27(b) as discussed above and in discussions to related sections of the rule, identified above. For example, in responding to public comments on its originally proposed follow-up testing requirement in item 12.6.3 of NUREG-1354, the Commission said that testing should be included as a means of achieving satisfactory management and medical determination of fitness and that it expected that follow-up testing would be administered following confirmed positive test results for those being returned to duty. These revisions are necessary to ensure that licensees comply with the Commission's original intent that unfit persons be removed and returned to duty only after being determined to be fit by management and a licensed physician who is qualified to make a medical determination of fitness.

***Staff Conclusion:* The revision to Section 26.27(b)(1) is a worthwhile change that the staff recommends be considered for adoption as an exception to the Backfit Rule. The revisions to sections 26.27(b)(3) and (5), with respect to physician determinations, are not backfits because they clarify, but do not change, current requirements.**

Section 26.27(b)(2): Conforming change regarding the threshold for alcohol policy violation

Revision: Section 26.27(b)(2) would be revised to clarify the fact that a positive confirmatory breath test for alcohol that indicates that the person had a blood alcohol

concentration that violated standards in section 26.24(h) must be presumed to be a violation of the licensee's FFD policy.

Purpose: This revision would be a conforming change regarding the threshold for alcohol policy violation.

Licensee Cost Reduction/Increase: No additional costs.

Backfit Rule Considerations: This revision would make no changes of substance and does not increase requirements. Instead, it conforms this section's requirements to those established in other revised rule sections [section 26.24(h), sections 2.4(g)(18) and (19) of Appendix A, and sections 2.7(f) and (g) of Appendix A].

***Staff Conclusion:* This revision is not a backfit because it is an administrative change.**

Section 26.27(b)(3): People suspended [and retained in a work status] must still be covered by behavioral observation, chemical testing, and sanctions for violations

Revision: Redesignated section 26.27(b)(3) [currently section 26.27(b)(2)] would be revised to clarify that people removed for violating the licensee's FFD policy must still be covered by behavioral observation, chemical testing, and sanctions for violations while suspended, but only if the worker continues employment with the licensee and reinstatement of access is anticipated.

Purpose: This clarification of existing requirements in sections 26.2 and 26.27(b)(2) would ensure that people suspended for at least 14 days for a first policy violation and kept within the scope of the rule are not omitted from the FFD program during the suspension period. This revision would stress the importance of maintaining the FFD program's deterrent value and ensuring that workers do not conduct activities prohibited by the program during their suspension periods. Also, this revision would ensure that those who are removed for violating the licensee's FFD policy are not "rewarded" for that unacceptable behavior. The modification to this revision, as originally proposed in the Commission's May 1996 Federal Register notice, would clarify that this requirement applies only to people who continue to be employed by the licensee with the expectation that they will regain access.

Licensee Cost Reduction/Increase: There would be no additional cost impacts.

Backfit Rule Considerations: No commenter stated that this clarification of current requirements in sections 26.2 and 26.27(b)(2) would increase licensees' burden. NEI did ask the NRC to clarify its intention as to: (1) whether suspended employees who are working during the suspension period away from the plant are to be covered by behavioral observation measures and chemical testing, and (2) whether suspended contractor/vendor employees should be subject to the requirements of the licensee's FFD program or of the requirements of their own contractor/vendor employer's FFD program when away from the licensee's plant and, therefore, no longer under the licensee's control. NEI also stated that, if this revision would require continued behavioral observation measures and chemical testing coverage of suspended employees when in a work status but at a location other than the plant, the proposed revision could prove impractical for licensees and would have to be justified as a backfit. The staff believes that this revision would clarify current requirements and creates no new burden for licensees. It would clarify that the rule's behavioral observation and chemical testing requirements continue to apply during the suspension period while the employee is referred to the EAP as currently required by section 26.27(b)(2) for assessment and plans for treatment and follow-up are made. Modifications to the revision would respond to commenters concerns by limiting this requirement to those with pending reinstatement of access and that such coverage need not necessarily be the licensee's program, which is a permissive relaxation.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would maintain the FFD program's deterrence and detection values during a worker's temporary removal.**

Section 26.27(c): Clarify that acts of subversion must be violations of policy and result in denial of unescorted access for 3 years and that the specific cause for removal must be provided in response to an inquiry

Revision: Section 26.27(c) would be revised to make it clear that subversion of the testing process is a violation of FFD policy and make it explicit that such a policy violation must lead to denial of unescorted access. The revision would also clarify that subversion is included in the events that must be recorded and provided in response to a suitable inquiry.

Purpose: The sanction for any act to subvert the testing process would be denial of unescorted access for a minimum of three years, a penalty that is consistent with that for a second confirmed positive drug test. This revision would reflect the seriousness of

subversion of the testing process as a policy violation and is consistent with current industry practice. The revision would also clarify the original intent of the rule and reflect the Commission's desire that all violations of FFD policy be accurately documented and reported in response to a suitable inquiry.

This revision would also address criticism of the lack of specific sanctions required for subversion of the testing process in the current FFD rule. In Niagra Mohawk Power Corporation v. IBEW (1998 WL 227981) the U.S. Court of Appeals for the Second Circuit determined that there was no clear public policy on adulteration or dilution of specimens despite "the level of public concern over the safety of the nuclear power industry." Therefore, an employee in a safety sensitive position who adulterated his specimen, whose second specimen was positive for cocaine, and had secreted vials of adulterants and clean urine in his locker should not have been terminated and must be returned to duty.

Licensee Cost Reduction/Increase: No significant cost impacts.

Backfit Rule Considerations: This revision is needed to establish a legally defensible basis to ensure that licensees are able to impose sanctions and take appropriate actions. The Commission requested that the revision concerning accuracy in documenting and reporting FFD policy violations be made in response to staff's discussion on proposed action item 11 of SECY91-293; item 6 of the SRM of November 7, 1992 stated "... the record should simply record the facts ...". This revision will not increase licensee costs, is consistent with current industry treatment of acts of subversion, and reflects the NRC's original intent that subversion be viewed as a serious FFD policy violation and that FFD events be recorded and reported properly. The staff notes that at least three States, Pennsylvania, Texas, and Nebraska, have criminalized acts of subversion of the testing process.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would ensure that an appropriate sanction is imposed for subversion of the testing process and that the basis for the removal is accurately documented and reported.**

Section 26.27(d): Clarify licensee handling of NRC contractors believed to be unfit

Revision: Section 26.27(d) would be revised to direct licensees to treat NRC contractors the same as NRC employees if licensees believe NRC contractors to be under the influence of any substance or otherwise unfit for duty.

Purpose: The current section 26.27(d) requires licensees to contact the Regional Administrator or the Operations Center if they have a reasonable belief that an NRC employee may be under the influence of any substance or otherwise unfit for duty, but is silent on NRC contractors. Since NRC contractors perform many of the functions as NRC employees, the NRC's need to be notified of its contractors' potential lack of fitness for duty is as great as its need to be notified of NRC employees' lack of fitness. The revision would require licensees to notify the NRC of NRC contractors' suspected lack of fitness, so that the NRC can take prompt corrective action.

Licensee Cost Reduction/Increase: None. As suggested by the fact that NEI requested this change, there would be some unquantifiable reduction in licensee burden, since the current rule could be read as requiring licensees' workforce to perform the difficult task of distinguishing between NRC employees and contractors.

Backfit Rule Considerations: This is a minor change to a licensee reporting requirement that was requested by NEI. The CRGR charter stipulates that new or revised information collection and reporting requirements are not considered to be backfits.

***Staff Conclusion:* This revision is not a backfit because it is an information collection and reporting requirement.**

Section 26.28: Clarify that the appeals process must be objective and conducted by persons not associated with the FFD program

Revision: This revision would clarify that the appeals process must be objective and conducted by persons not associated with the FFD program.

Purpose: The NRC staff is aware that, in some instances, licensees' appeals processes have not been as fair and impartial as the Commission originally intended. For example, some licensees have allowed the people responsible for making the initial determination of FFD policy violation to conduct the appeals of those determinations. Such practices can undermine the effectiveness of FFD programs by diminishing employees' perception of the fairness of the programs. Therefore, section 26.28 which currently requires an

impartial review process would be revised to clarify the NRC's intent that appeals must be objective fact finding processes and conducted by people not associated with the FFD programs. The other purpose of the revision is to create consistency with the NRC's access authorization program. In 10 CFR 73.56(e), the Commission requires that licensees' procedures for reviewing unescorted access denials be "... an objective review ..." and "an impartial and independent ... review." This revision of section 26.28 would be intended to clarify that the Commission expects similar levels of objectivity and fairness in the FFD and access authorization programs. However, the staff does not intend that "independence" be achieved by obtaining the services of persons outside the licensee's organization.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: When it originally proposed its FFD requirements, the Commission stated that licensees' appeals procedures should be conducted "in accordance with due process and fundamental fairness" (53 FR 36818; September 22, 1988). It is obvious that, for appeals to achieve these goals, they must be conducted in an objective manner by people who have some independence from the FFD program. The staff is aware that some licensee appeals procedures do not provide these safeguards for workers' rights. This revision would rectify that situation as well as create consistency with similar appeals provisions in the access authorization program.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would assure the due process and fundamental fairness that the Commission originally intended be an integral part of licensees' appeals processes and it would create consistency between the FFD rule's appeals requirements and those of the NRC's access authorization requirements.**

Section 26.28: Clarify that an individual may submit additional relevant information

Revision: Section 26.28 would be revised to make it clear that employees appealing FFD policy violation determinations must be allowed to submit, as part of the appeals process, any relevant information that supplements the information on which the violation determination was based.

Purpose: This revision would recognize that any decisions that can affect licensee employees' careers must be based on information that is complete and accurate. Therefore, section 26.28, which currently requires notice and an opportunity to respond

would be revised to clarify that the opportunity to respond includes submittal of additional relevant information.

Licensee Cost Reduction/Increase: No cost impact.

Backfit Rule Considerations: This revision would not increase licensee costs and reflects the NRC original intent that appeals take advantage of all relevant information.

Staff Conclusion: This revision is not a backfit because it clarifies, but does not change, a current requirement.

Section 26.29(b) and (c): Clarifying and conforming edits

Revision: These revisions would make very minor edits.

Purpose: Assure conformance with other sections of the rule.

Licensee Cost Reduction/Increase: None.

Backfit Rule Considerations: These are minor edits.

Staff Conclusion: These revisions are not backfits because they clarify, but do not change, current requirements.

Section 26.70(b): Clarifies the records that NRC can inspect

Revision: Section 26.70(a) would be revised to state that licensees' contractors and vendors shall allow NRC representatives to inspect its premises, activities and personnel and inspect, copy or take away copies of relevant records. Section 26.70(b)(2) would be revised to state that licensees' contracts must include provisions that will ensure that documents, records, and reports from licensee's contracted service providers are among the types of records that NRC representatives may inspect.

Purpose: Section 26.70(a) currently requires licensees to allow NRC representatives access to inspect the licensee's premises, activities and personnel, and to inspect and copy relevant licensee records. However, that section is silent on the NRC's ability to inspect licensee contractors and vendors such as HHS-certified laboratories. Section 26.70(b)(2) currently requires that licensees' contracts include certain provisions concerning the NRC's access during an inspection to FFD program facilities, activities,

personnel, and records. Some contractors providing FFD services to licensees, such as HHS-certified laboratories or contracted MRO services, have been unwilling to provide appropriate documents to NRC inspectors. These revisions would assure that these service providers will permit NRC access to their laboratories and make certain records available to NRC representatives.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: Section 26.70(b)(2) currently states that the licensee contracts must include a provision that duly authorized representatives of the Commission may inspect, copy, or take away copies of documents related to implementation of the FFD program including contracted activities. This revision would make explicit the Commission's long-standing expectation that licensees' FFD service contractors make documents, records, and reports related to the contracted services available to NRC representatives. To the extent that licensees have not made this obligation explicit in their written agreements with their service providers, or that some contracted service providers have been reluctant to actually provide this information, this revision would assure compliance.

***Staff Conclusion:* This revision fits within the Backfit Rule's compliance exception.**

Sections 26.71(b) and (c): Conforming edit (and new clarifying edits)

Revision: Section 26.71(b) would be revised to require a 5-year records retention period for records of all FFD policy violations, not just those associated with positive test results. Another proposed revision to this section would assure that records of FFD policy violations that may be challenged are retained until completion of all legal proceedings related to the violations. Section 26.71(c) would be revised to conform references to changes in other parts of the rule, primarily sections 26.27(b) and (c).

Purpose: In a number of sections, including section 26.71(b), the rule currently refers to "positive" test results. Therefore, a strict reading of this section's records retention requirement could lead to licensees retaining records of confirmed positive test results but disposing of records of refusals to take a test, subversion of the testing process, and selling or possession of drugs on site. This change would revise the rule to explicitly state that licensees are to retain records of any type of FFD policy violation so that they are available if needed to respond to later suitable inquiries or to provide information in administrative or other employment actions. It may also alleviate situations in which

licensees are needlessly saving records of positive test results that were determined not to be violations (e.g., specimens positive for opiates due to ingestion of poppy seeds). An additional minor edit would assure that records of FFD policy violations that may be challenged in legal proceedings are retained until the completion of the legal proceeding. This revision is being proposed in response to a public comment that noted the possibility that licensees could dispose of records of violations after five years, as section 26.71(b) currently allows, even if those records are needed in ongoing or upcoming legal proceedings.

Section 26.71(c) currently requires licensees to retain records of persons who are removed from activities within the scope of Part 26 for three or more years pursuant to section 26.27(b) or 26.27(c) requirements. Wording changes in those latter sections would stipulate that licensees are to revoke employees' authorization to perform duties to section 26.27 covered by Part 26 following certain specified infractions rather than removing them from activities covered by Part 26 as these sections currently require. This proposed revision to section 26.71(c) would conform this section's wording to those changes to section 26.27 by changing the reference to the records to be retained to those pertaining to revocations of authorization to perform duties covered by Part 26.

Licensee Cost Reduction/Increase: There would be no significant cost impact. Most licensees are already retaining records of all FFD policy violations, not just those associated with confirmed positive test results. Licensees have always had to retain records of all types of FFD policy violations to be able to rely on this information in legal proceedings.

Backfit Rule Considerations: All information collection and records retention requirements contained in this rulemaking have been approved by the Office of Management and Budget (OMB) approval number 3150-0148. The CRGR charter stipulates that new or revised information collection and reporting requirements are not considered to be backfits. The revision to section 26.71(c) would be a minor conforming change to reflect revisions elsewhere in the rule.

Staff Conclusion: This revision is not a backfit because it is an information collection and reporting requirement.

Section 26.71(d): Include number of subversion attempts by type in program performance reports

Revision: This revision to section 26.71(d) would require licensees to include the number of subversion attempts by type in program performance reports.

Purpose: Section 26.71(d) currently lists the specific types of data that licensees must compile and report to the NRC. This section would be revised by listing the number of subversion attempts by type as another set of data that would be reported to the Commission. The Commission, in its SRM of March 22, 1989, directed the staff to ensure that it collects adequate data so that licensee programs can be analyzed, the effectiveness of the rule can be assessed, and appropriate improvements or changes can be made. This revision would be consistent with several other rule revisions that emphasize the need for licensees to limit subversion of the testing process and would provide the staff with valuable information about the industry's success in this regard and whether any additional improvements to licensees' programs or the rule are needed.

Licensee Cost Reduction/Increase: As a practical matter, this revision would create no new costs because licensees are currently providing this information in narrative form in their program performance reports as a program success.

Backfit Rule Considerations: The CRGR charter stipulates that new or revised information collection and reporting requirements are not considered to be backfits.

***Staff Conclusion:* This revision is not a backfit because it is an information collection and reporting requirement.**

Section 26.73(a): Conforming changes

Revision: Section 26.73(a) would be revised by adding FFD program personnel as a class of people whose improper acts are to be reported to the Commission.

Purpose: Section 26.73(a) currently requires licensees to report to the Commission significant FFD events including the improper acts of certain classes of people covered by the rule. As discussed in Group IIIB, a proposed revision to section 26.2(a)(4) would ensure compliance with the Commission's original intent that FFD program personnel must be included within the scope of the rule. This revision to section 26.73(a) would conform this section to the change made in section 26.2(a)(4) by stipulating that improper acts by FFD program personnel are to be reported to the Commission.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: This revision would create no new requirements as licensees have always had to report the improper acts of certain specified classes of people whose fitness and integrity are essential for power plant and FFD program operations. It would be a minor change that conforms this section with the proposed revision to section 26.2(a)(4) and ensures that FFD program personnel are among those whose fitness and integrity must be assured. Licensees have always had to retain records of all types of FFD policy violations to rely on this information in legal proceedings. The CRGR charter stipulates that new or revised information collection and reporting requirements are not considered backfits.

***Staff Conclusion:* This revision is not a backfit because: (1) it is an information collection and reporting requirement, and (2) it clarifies, but does not change, a current requirement.**

Section 26.73(a): Provides additional examples of significant FFD events

Revision: Section 26.73(a) would be revised to provide additional examples of significant FFD events to be reported, viz.: (1) any act that casts doubt on the integrity of the FFD program, including but not limited to acts that cast doubt on the honesty and integrity of FFD program personnel covered by the rule; (2) the distribution or presence of illegal drugs or alcohol within the protected area (in addition to the current examples of sale, use, or possession of illegal drugs); and (3) FFD violations by operators, supervisors, and FFD program personnel (rather than only confirmed positive test results) and arrest for sale, distribution, use, or possession of illegal drugs on or off site.

Purpose: Section 26.73(a) currently requires licensees to report significant FFD events which are not limited to the examples provided. The events which would be added as examples would provide additional guidance regarding the types of events that are considered significant. The staff's knowledge of the occurrence of these events would be useful for formulating public policy and for responding in a timely fashion. This revision would also make it clear that the NRC expects licensees to report all significant FFD events and reaffirms that the trustworthiness of FFD program personnel continues to be of concern to the NRC.

Licensee Cost Reduction/Increase: Insofar as its impact on licensee burden is concerned, licensees have always been required to report significant FFD events to the

NRC. In those rare instances in which the honesty and integrity of FFD program personnel come into question, licensees will only have to make a simple phone call to report the events to the NRC staff. In the almost eight years since the rule was implemented in January 1990, only nine incidents involving FFD program personnel have been reported. Also, the NRC staff believes that the number of additional reports of significant events, such as sale or distribution of drugs on site, will be minimal. Therefore, the future cost of reporting these events would obviously be minimal. This is reflected in the staff's estimate of additional annual costs of about \$70 per site, resulting in approximately \$7,000 in additional annual costs for the industry.

Backfit Rule Considerations: NEI asserted that the proposed revision would single out FFD program personnel as a group that must be watched more closely and regulated more tightly than other people covered by the rule. Since FFD program personnel are no less trustworthy than others covered by the rule, NEI believes this new section to be superfluous. This appears to be more of an NEI policy recommendation than a backfit assertion.

Section 26.73(a) already requires licensees to report significant FFD events. Reportable events are not limited to the examples involving licensed operators and supervisory personnel which this section has always provided. Instead, this revision would clarify information collection and reporting requirements by providing additional examples for the NRC's long-standing requirement that significant events involving FFD program personnel are among the types of events that licensees must report, as currently required by section 26.73(a). This revision is necessary to bring licensees into compliance with the current reporting requirements.

The CRGR charter stipulates that new or revised information collection and reporting requirements are not considered to be backfits.

Staff Conclusion: This revision is not a backfit because (1) it is an information collection and reporting requirement, and (2) it clarifies, but does not change, an existing requirement.

Section 26.80(c): Conforming edit

Revision: Section 26.80(c) would be revised to eliminate a currently existing reference to the fact that Appendix A requires licensees to audit their HHS-certified laboratories. A second revision, prompted by public comment, would clarify that licensees must take corrective action in response to audit findings.

Purpose: FFD program audit requirements would now be specified in section 26.80(a), not divided between section 26.80 and section 2.7(n) of Appendix A as they are now. Therefore, the currently existing reference in 26.80(c) to this audit requirement in Appendix A would no longer be necessary.

The second revision concerning corrective actions would be made to assure that problems detected in audits are not repeated. The current 26.80(c) requires licensees to document the resolutions of audit findings and corrective actions. This revision responds to a public comment that noted that section 26.80(c) currently requires only that licensees document the results of audits, but does not explicitly require licensees to take corrective action even if the audit report recommends such corrective action. The revision paraphrases and therefore reiterates the requirements of Criterion XVI in Appendix B to 10 CFR Part 50, which requires licensees to take appropriate corrective action.

Licensee Cost Reduction/Increase: Neither revision would create new costs.

Backfit Rule Considerations: The first revision would create an administrative change but make no change of substance to the rule. The newly proposed revision concerning corrective actions would reiterate current requirements contained in Appendix B to Part 50 to make explicit in 26.80(c) the need to take corrective action when audits detect programmatic problems. By doing so, it would create no new requirement but, instead, clarify a current requirement.

***Staff Conclusion:* The first revision is not subject to backfit requirements because it is an administrative change. The second revision is not a backfit because it clarifies, but does not change, a current requirement.**

Section 1.1 of Appendix A: Minor clarifying edits

Revision: Section 1.1 of Appendix A would be revised by changing its subsection designators from numbers to letters. Another revision would add the word "other" in reference to the provisions of these guidelines.

Purpose: The first revision is necessary to conform this section to the standard numbers and letters subsection designator sequence in the rest of Appendix A. The other revision would provide a needed, but very minor, grammatical clarification.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: The proposed change of subsection designators is a minor administrative revision that is needed to conform this section with the rest of Appendix A. The wording change is a minor clarifying edit that does not impose a backfit as defined by the Backfit Rule.

Staff Conclusion: These revisions are not backfits because: (a) they are administrative changes and (b) they clarify, but do not change, existing requirements.

Section 1.2 of Appendix A: Delete or relocate definitions and add definition of limit of detection (LOD)

Revision: Revisions to section 1.2 of Appendix A would delete some definitions (many of which are to be moved to section 26.3) and would add a definition of "Limit of Detection."

Purpose: Most of the words that are currently defined in this section of Appendix A are used in the main body of the rule and, therefore, should be defined in section 26.3. Repeating those definitions in Appendix A is unnecessary. The term "Limit of Detection" would be added in support of other changes to the appendix.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: Moving the definitions from Appendix A to the main body of the rule and creating a new definition would create no changes of substance. Instead, these revisions would be administrative changes that are not subject to Backfit Rule requirements.

Staff Conclusion: These revisions are not backfits because they are administrative changes.

NEW: Section 1.2 of Appendix A: Minor clarifying edits

Revision: Section 1.2 of Appendix A currently contains definitions of several terms that are used in Appendix A. This section would be revised to acknowledge the existence of definitions of other terms in section 26.3.

Purpose: This revision is intended to inform those using the appendix that most definitions are provided in section 26.3.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: This is a minor edit that would make it clear that section 26.3 contains other definitions.

Staff Conclusion: This revision is not a backfit because: (a) it is an administrative change and (b) it clarifies, but does not change, an existing requirement.

Section 2.1(a) of Appendix A: Add return-to-duty testing to the types of testing required elsewhere in the rule [formerly: Sections 2.1(a), (b) and (e) of Appendix A: Conforming and minor edits]

Revision: Section 2.1(a) of Appendix A would be revised to add return-to-duty testing to the list of required types of testing in section 2.1(a) of Appendix A. This is a conforming change associated with the proposed adoption of a new section 26.24(a)(5), which would add return-to-duty testing as a fifth type of required testing. This new section is discussed above in Group IIIA.

Purpose: This revision to section 2.1(a) of Appendix A would conform this section with the revision to section 26.24(a) which added return-to-duty testing as the fifth type of testing used to detect illegal drug use and the misuse of alcohol.

Licensee Cost Reduction/Increase: There would be no cost impact associated with this conforming change. The costs associated with return-to-duty testing are accounted for in the discussion on section 26.24(a).

Backfit Rule Considerations: This revision to section 2.1(a) would be only a minor edit that would conform this section to the revised section 26.24(a). By itself, this proposed revision is a minor clarifying edit that raises no backfit issues separate from those considered in relation to the proposed revision of section 26.24(a)(5).

Staff Conclusion: This revision is not a backfit because it clarifies, but does not change, an existing requirement.

Sections 2.1(b) and (e) of Appendix A: Conforming and minor edits [formerly: Sections 2.1(a), (b) and (e) of Appendix A: Conforming and minor edits]

Revision: Section 2.1(b) of Appendix A would be revised to provide licensees the discretion to test, as part of return-to-duty and for-cause testing, the presence of substances suspected of being abused. The revision to section 2.1(e) would correct a typographical error.

Purpose: Currently, sections 26.10, 26.24(b) and (c), 26.27(b), sections 1.1(2) and 2.1(a) of Appendix A, and guidance in the HHS "Medical Review Officer Manual" authorize licensees to test urine specimens for any substances suspected of being abused during a "for-cause" test. This licensee discretion is provided to address situations there is some "probable cause" to believe that the person being tested has been abusing alcohol or drugs or has a history of substance abuse. With the proposed addition of return-to-duty tests to Part 26 and the proposed clarifications to follow-up testing (see Groups IIA and IIIB above), the staff believes that similar discretion should also be afforded to licensees when conducting these tests to also test for substances suspected of being abused to determine the cause of impairment or erratic behavior, and may consider any detected drugs or metabolites.

Licensee Cost Reduction/Increase: There would be no cost impact, since the revisions would clarify the permissive scope of testing that licensees may conduct as part of for-cause, return-to-duty and follow-up testing.

Backfit Rule Considerations: The current section 2.1(b) of Appendix A (and the revision) is permissive and provides licensees and their MROs with the flexibility needed when conducting for-cause testing to identify the cause of apparent impairment or erratic behavior that could endanger safety. The proposed revision to section 2.1(b) would extend this flexibility to return-to-duty testing and follow-up testing. While it would not add any new requirements, this revision would clearly state in one section the important idea, which was communicated in the HHS Medical Review Officers Manual, that public safety may indicate a need to go beyond the five main proscribed illegal drugs.

***Staff Conclusion:* This revision is not a backfit because it does not impose any requirement upon licensees, but provides additional flexibility to the licensees to address safety issues.**

Sections 2.2(a) and (d) of Appendix A: Minor and conforming edits

Revision: Sections 2.2(a) and (d) would be revised by substituting "must" for "shall" and changing "sample" to "specimen."

Purpose: As in several other sections throughout the rule, changing "shall" to "must" would clarify the mandatory nature of this section's requirements. Changing "sample" to "specimen" would conform this section to the common use of "specimen" elsewhere in the rule as well as to common usage in drug testing generally.

Licensee Cost Reduction/Increase: There would be no cost impact.

Backfit Rule Considerations: These revisions would be minor clarifying edits that would create no new requirements.

***Staff Conclusion:* These revisions are not backfits because they are minor clarifying edits to the current rule.**

Sections 2.3(b) and 2.3 of Appendix A: Fitness-for-duty program personnel tested by independent personnel to the extent practicable and minor clarifying edits

Revision: A new section 2.3(b) of Appendix A would be added to require that FFD program personnel [who must be tested under section 26.2(a)(4)] must be tested by personnel independent of FFD program administration to the extent practicable. Minor clarifying edits would also be made to the rest of section 2.3.

Purpose: Section 2.3(1) [section 2.3(a) in the revised rule] currently provides that "Supervisors, co-workers, and relatives of the individual being tested shall not perform any collection, assessment, or evaluation procedures." However, this provision does not explicitly apply to FFD personnel being tested, although a plain reading of the language would apply it to FFD personnel. On the other hand, literal application of the language would be impossible, since it is clear that someone qualified to perform and interpret FFD tests must conduct the testing of FFD personnel. Thus, the proposed requirement is intended to reduce the possibility of FFD program personnel being responsible for testing themselves or their close colleagues, but recognizes that such independence should be followed only "to the extent practicable." A proposed new section 2.3(4) of Appendix A would have reiterated the requirements of section 26.2(a) concerning the testing of FFD program personnel. Since it is not necessary, the proposed new section 2.3(4) has been withdrawn.

Licensee Cost Reduction/Increase: There would be only a minimal or no cost increase.

Backfit Rule Considerations: This revision would reiterate and clarify the current requirement in section 2.3(1) as applied to FFD personnel.

NEI urged the NRC to further revise section 2.3 of Appendix A to allow two-party collaboration to conduct testing of FFD program personnel when people who are independent of the FFD program administration are not readily available to conduct testing. Two-party collaboration would involve two certified collectors working together to obtain specimens, thus avoiding potential collusion with the FFD program personnel being tested. According to NEI, collaboration in specimen collection is an accepted means of preventing collusion and allowing it would provide licensees with flexibility to meet this new requirement. If the NRC declines to adopt this recommendation, NEI asked that the requirement that FFD program personnel shall be tested by personnel independent of the FFD program administration be justified as a backfit.

The staff agrees with NEI that two-party collaboration can be a useful means of conducting testing of FFD program personnel when people who are independent of the FFD program administration are not readily available. While two-party collaboration should be used only sparingly, it does fit within the purview of the currently proposed wording of this section that requires testers be independent of FFD program administration "to the extent practicable." Since NEI's requested change is already accommodated by the currently proposed revision, the staff concludes that NEI's recommendation raises no backfit issue.

***Staff Conclusion:* This revision is not a backfit because it clarifies, but does not change, a current requirement.**

Section 2.4(f)(1) and 2.4(f) of Appendix A: Current or previous specimen that fails to meet normal standards constitutes a reason to require observed testing and minor clarifying changes

Revision: The current section 2.4(f) of Appendix A establishes privacy requirements for collecting urine specimens and describes the circumstances under which observed collections are authorized. A new section 2.4(f)(1) would clarify the privacy requirements in the event of suspected subversion. It would stipulate that a urine specimen that fails to meet acceptable standards, or is of questionable validity, constitutes a reason to believe that the donor may be trying to subvert the testing process. In such cases, licensees will have the discretion to require an observed specimen collection for such people on

subsequent testing occasions. This revision would also make clear, however, that questionable specimens that have been subsequently determined through special processing and MRO review not to indicate a violation of FFD policy should not compromise the employee's privacy at a later specimen collection. Minor clarifying changes would also be made to the rest of section 2.4(f).

Purpose: Section 2.4(f) has always allowed licensees to conduct observed urine collections when "there is a reason to believe that a particular individual may alter or substitute the specimen to be provided." The new section 2.4(f)(1) would accomplish two purposes. First, it would clarify that an earlier presentation of a urine specimen that either failed to meet the section 2.4(g)(15) standards for an acceptable specimen or was determined to be of questionable validity under the provisions of section 2.7(e) constitutes a "reason to believe" that the person may alter or substitute the specimen to be provided on the current testing occasion. Second, this revision would protect employees' privacy in some instances by requiring licensees to take into account information gained about a urine specimen that had been subject to special processing mandated by section 2.7(e) because it appeared to be of questionable validity. In cases where such special processing indicated that the person actually had not submitted an adulterated or diluted specimen, licensees would be on notice that the prior submission of a specimen of questionable validity is not to be considered a "reason to believe" that the person may alter or substitute the specimen to be provided on the current testing occasion. This, in effect, will reduce the need for observed collections by taking advantage of the information that will now be available to MROs due to special processing, including testing at the limit of detection.

Licensee Cost Reduction/Increase: This change may produce a minimal decrease in licensee burden by reducing the incidence of observed specimen collection following a questionable specimen that special processing indicates to be a non-violation.

Backfit Rule Considerations: Section 2.4(f) of Appendix A currently authorizes licensees to conduct observed urine collections when "there is a reason to believe that a particular individual may alter or substitute the specimen to be provided." The section also currently states the circumstances that can constitute such a "reason to believe." This revision would clarify licensees' current authority to conduct observed collections by providing more explicit guidance as to what specimen attributes are grounds for requiring subsequent observed collections. It would also tend to reduce the number of observed collections that are currently required. It would do this by noting that specimens that appear to be of questionable validity but are subsequently found to not indicate a FFD policy violation are not to be used as a reason for observed collections when the person is

tested on later occasions. In combination with the new special processing requirements of section 2.7(e), this revision will relieve licensees of the obligation to conduct observed specimen collections in certain situations where they would normally conduct observed collections under the current rule.

Staff Conclusion: This revision is not a backfit because it clarifies, but does not change, a current requirement and may provide a permissive relaxation of a current requirement. It also constitutes a "worthwhile improvement" because it protects employees' privacy under certain circumstances.

Sections 2.4(g) and (g)(14), (15), (18), (19), (20), (23), (24), and (27) of Appendix A: Conforming and clarifying changes

Revision: These revisions would conform to other revisions regarding what constitutes an acceptable specimen (e.g., with regard to temperature) and would make other minor edits (e.g., "shall" to "must").

Purpose: To conform to and clarify requirements for an acceptable urine specimen.

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: These would be minor conforming or clarifying edits.

Staff Conclusion: These revisions are not backfits because they are administrative changes or clarify existing requirements and do not impose any backfits as defined in 10 CFR 50.109(a)(1).

Sections 2.4(g)(23), (h) and (i) of Appendix A: Require secure sealing of specimen bottle and clarify sealing and labeling requirements

Revision: These revisions would clarify current requirements regarding measures to prevent undetected tampering of specimens. The revision would clarify the requirements for the secure sealing of specimen bottles and clarify the requirements for sealing and labeling of tamper-evident shipping containers.

Purpose: Sections 2.4(g)(22), 2.4(h) and 2.4(i) currently require that bottles and shipping containers be securely labeled and sealed. The revisions would clarify these requirements.

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: This is a clarification of existing requirements.

***Staff Conclusion:* These revisions are not backfits because they clarify, but do not change, current requirements.**

Section 2.4(i) of Appendix A: Continue to require specimens to be shipped to HHS-certified laboratory or cooled within 6 hours of collection as previously required by section 2.7(c) and 2.4(i) and (j) conforming changes

Revision: One revision would add language to section 2.4(i) of Appendix A to require that specimens be shipped to the HHS-certified laboratory or cooled within 6 hours of collection as previously required by section 2.7(c). An additional modification to this section would require licensees to take appropriate and prudent action to minimize specimen degradation and note that the above requirements are a minimum to achieve this goal. Other modifications to section 2.4(i) and modifications to section 2.4(j) would be conforming changes.

Purpose: Section 2.7(c) currently requires licensees to chill specimens that are not to be shipped to a HHS-certified laboratory for testing within six hours of collection at a temperature of no more than 6°C/43°F. This requirement would be restated in section 2.4(i) to emphasize the importance of decreasing the chance that specimens will be degraded between the time they are collected and the time they are screened and confirmation tested. It is appropriate to reiterate this requirement in section 2.4(i) because it is in that section that licensees' responsibilities for preparing and transporting specimens to the testing laboratories are stated. The additional modification would provide flexibility to allow licensees to take other actions to minimize specimen degradation. The conforming changes to sections 2.4(i) and (j) would delete wording made obsolete by other rule changes.

Licensee Cost Reduction/Increase: No cost impact.

Backfit Rule Considerations: The revision to section 2.4(i) regarding specimen shipment or cooling would be a restatement of a current requirement -- it creates no new requirements and will have no impact on licensee burden. The other revisions to sections 2.4(i) and (j) are minor conforming changes.

Staff Conclusion: This revision is not subject to backfit requirements because it is an administrative change.

Section 2.5(a)(5) of Appendix A: Minor clarifying edits

Revision: Change "shall" to "must".

Purpose: Administrative change to conform with language used in NRC regulations.

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: This is an administrative change.

Staff Conclusion: This revision is not a backfit because it is an administrative change.

Sections 2.7(b), (d), (f), (g), (h), (i), (k), (l), and (m) of Appendix A: Minor clarifying edits

Revision: These revisions would be minor clarifying edits.

Purpose: A number of changes would be made to make the use of terms more consistent throughout the rule (e.g., "screening test" always used instead of sometimes referring to the screening test as the "initial" test). In addition, "shalls" are changed to "musts".

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: These are minor edits to increase rule consistency.

Staff Conclusion: This revision is not a backfit because it is an administrative change.

Section 2.7(c) of Appendix A: Require chilling or testing within one day of arrival at HHS-certified laboratory

Revision: Section 2.7(c) of Appendix A would be revised to require that specimens that will not be screen tested and, if appropriate, confirmatory tested within one day of arrival at the laboratory, must be stored in a chilled condition.

Purpose: Section 2.7(c) of Appendix A currently requires that specimens that do not receive an initial test within seven days of arrival at the laboratory shall be placed in refrigerated storage. The reason for this requirement was to prevent specimens from degrading and providing false negative test results, and it was believed that an unrefrigerated period of 7 days would be permissible. This revision would respond to research data and anecdotal evidence which indicates that the potential for significant drug or metabolite deterioration when specimens are shipped or stored at relatively warm temperatures may occur over a shorter time period than previously believed. This deterioration can cause specimens containing drugs or metabolites over the cut-off level at the time they were collected to be found negative in screening or confirmation tests conducted several days after the collection. The research shows that this degradation can occur 72 hours after collection if the specimen is not chilled. For example, an MRO reported that 19 of the 21 presumptive positive results from on-site screening tests failed to be confirmed by the laboratory due to specimen degradation (see Appendix B of NUREG/CR-5784). Also, the reasons given for unsatisfactory results of blind performance tests reported by the HHS-certified laboratories are that the blind specimens degraded below the cut-off levels. (Blind specimen providers now add preservatives to reduce specimen degradation.) A pilot test conducted by the NRC detected a significant level of cocaine metabolite deterioration after 36 hours. Also, a study by one licensee showed a definite decrease in the concentration levels of THC in specimen bottles stored at room temperature for one week, in some cases the degradation was more than half (see Chapter 9 of NUREG/CR-6470). Therefore, the proposed revision is necessary to minimize the time that a specimen is not chilled between collection and testing.

Licensee Cost Reduction/Increase: This revision would create either no, or very minimal, additional licensee burden. The staff is aware that it is currently very common practice among HHS-certified laboratories to test specimens within 24 hours of receipt. In any case, as currently stated this section already requires HHS-certified laboratories to chill specimens and having to do so in those few cases when the laboratories do not conduct tests within 24 hours of receipt should cause virtually no added expense.

Backfit Rule Considerations: Section 2.7(c) of Appendix A states that specimens that do not receive an initial (i.e., screening) test within 7 days must be refrigerated. The 7-day standard was initially established based on the assumption that specimen deterioration would adversely affect the test results after that 7-day period. Research and licensee experience has shown that there is a potential for specimen degradation over a shorter period of time. Therefore, this revision is needed to ensure that valid testing results are obtained so that persons abusing drugs are identified and removed from duties that could affect public health and safety.

Staff Conclusion: This revision is a worthwhile change which the staff recommends be considered for adoption as an exception to the Backfit Rule. The proposed revision would avoid specimen degradation by reducing the time period for which samples would be allowed to remain unrefrigerated. The current rule's refrigeration standards were based upon unquantified assessments of specimen degradation which subsequent research has shown are incorrect.

Section 2.7(d) of Appendix A: MRO to report adulteration or dilution to management immediately

Revision: Section 2.7(d) of Appendix A would be revised to require MROs to report adulteration or dilution to management immediately.

Purpose: Section 2.7(d) of Appendix A currently requires any evidence of adulteration or dilution to be reported to the MRO, but does not require the MRO to report that evidence to management. Section 26.24(e) currently requires the MRO to report "test results" to licensee management, and section 2.9(c) of Appendix A currently requires MROs to report "verified positive test results" to licensee management but does not specifically require the MRO to report test results that are evidence of adulterants or dilution. This revision to section 2.7(d) would make it clear that evidence of adulteration or dilution of specimens are within the scope of "test result" and "positive test result" so that the MRO must report such adulteration or dilution evidence to licensee management immediately.

Licensee Cost Reduction/Increase: There would be no cost impact, since MROs are already required to promptly report to licensee management positive test results, and the added increment of burden associated with the reporting of adulteration or dilution would be nil. Moreover, the staff is aware that it is common practice for licensee management to be promptly informed of any subversion of the testing process noted during the collection process [an interpretation of the intent of section 2.4(j) of Appendix A], indications of tampering discovered during on-site testing [required by section 2.7(b)(1) of Appendix A] and for MROs to report to licensee management any evidence of adulteration or dilution reported by HHS-certified laboratories.

Backfit Rule Considerations: Since the current rule provides for MRO reporting to licensee management of "test results," and evidence of adulteration or dilution is a possible finding of a conducted test, it can be argued that the current rule requires MROs to report to licensee management all tests where there are evidence of adulteration or dilution. Thus, the proposed revision simply clarifies the existing requirement and does not impose a new requirement on licensees. In any event, it is also apparent from the

requirement that MROs report "test results" and "positive test results" to licensee management that the Commission intended MROs to report all FFD violations including sample adulteration and dilution. Adulteration and dilution are clear evidence of subversion of the FFD program and as such represent a significant health and safety concern. Thus, reporting of adulteration and dilution to licensee management would ensure that the licensee promptly removes from unescorted access an individual who has committed a FFD violation and is necessary to assure that the general performance objectives in Section 26.10 are achieved.

Staff Conclusion: This revision could be considered to not be a backfit because it clarifies, but does not change, a current requirement. Alternatively, it can be viewed as fitting within the Backfit Rule's compliance exception.

Sections 2.7(f) and (g) of Appendix A: Standards for BAC established

Revision: These revisions would add footnotes to the screening and confirmatory cutoff level charts in sections 2.7(f) and (g) of Appendix A, respectively, to define the specifications to be used when determining blood alcohol concentration.

Purpose: The current standards for determining BAC are included in the definitions in section 1.2 of Appendix A. The standards are more appropriate for sections 2.7(f) and (g) of Appendix A, and have been removed from the definitions. The specifications that would be added are those normally used in determining BAC. Therefore, this revision would make no changes of substance but merely state explicitly standards that have always been in effect.

Licensee Cost Reduction/Increase: There is no cost impact because the BAC standards are currently in effect and are not changed by this revision.

Backfit Rule Considerations: This revision clarifies existing standards, and uses the standard currently included in the definition of "BAC" in section 1.2 of Appendix A.

Staff Conclusion: This revision is not a backfit because it clarifies, but does not change, a current requirement.

Section 2.7(h) of Appendix A: Evidence of subversion must be reported by HHS-certified laboratory

Revision: Section 2.7(h)(1) [currently 2.7(g)(1)] of Appendix A would be revised to clearly state that HHS-certified laboratories must report any indications of adulteration, dilution, or tampering to the MROs.

Purpose: Section 2.7(g)(1) of Appendix A currently requires that HHS-certified laboratories report "test results" to the MRO. Section 2.7(d) states: "Any evidence of adulteration or dilution...shall be reported to the MRO." Despite the apparently clear direction in the current rule, some licensees expressed concern that the rule does not require the laboratories to report the results of specimen validity tests (adulteration and dilution). Accordingly, the rule would be revised to state that the HHS-certified laboratory report to the MRO shall contain "any indications of...adulteration, or dilution that may be present."

Sections 2.7(b)(1) of Appendix A currently requires that the HHS-certified laboratory report "[a]ny direct evidence of tampering....to the licensee." As with adulteration and dilution, some licensees expressed concern that the rule does not require the laboratories to report the results of tampering despite the apparently clear direction in the current rule. Accordingly, the rule would also be revised to state that the HHS-certified laboratory report to the MRO shall contain "any indications of *tampering*, adulteration or dilution that may be present."(emphasis added).

Licensee Cost Reduction/Increase: There is no cost impact, because the HHS-laboratory are required by existing requirements to report evidence of adulteration, dilution and tampering to MROs.

Backfit Rule Considerations: The revisions would clarify the existing requirement that HHS-certified laboratories must report evidence of adulteration, dilution and tampering. No new requirements are imposed by this change.

***Staff Conclusion:* The revision is not a backfit because it clarifies, but does not change, a current requirement.**

Section 2.7(h) of Appendix A: Laboratory retention of original chain-of-custody form

Revision: Section 2.7(h)(5) [formerly 2.7(g)(5)] would be revised to clarify that HHS-certified laboratories, rather than the licensee, shall retain the original copies of chain-of-custody forms (now referred to as custody-and-control forms) that accompanied the specimens that were tested by the laboratory.

Purpose: Section 2.2(a) of Appendix A currently requires that the original of the chain-of-custody form accompany the specimen to the HHS-certified laboratory. Section 2.7(g)(5) of Appendix A currently requires that the HHS-certified laboratory send a “certified copy” of the original chain-of-custody form to the MRO when it sends the test report to the MRO (implying that the original is retained by the laboratory). However, these sections are silent as to whether the laboratory must retain, or may dispose of, the original chain-of-custody form. However, the fact that the current rule requires the HHS-certified laboratory to send a “certified copy” rather than the original chain-of-custody form suggests that the laboratory should retain custody. Licensees have suggested that they, rather than the HHS-certified laboratory, should retain the original form and that the current rule be changed to make this clear. The revision would clarify that the HHS-certified laboratories rather than the licensee should retain custody of the original form. The HHS-certified laboratories, not the licensees, retain custody of the samples and would be responsible pursuant to section 2.7(o)(5) for providing expert testimony concerning the test results including the chain-of-custody form. Moreover, sending the original form back to the licensee would involve some incremental risk of the form being lost in the mail; and having the original at one site and a copy at a different site provides some measure of redundancy if the documents at one site are damaged or destroyed.

Licensee Cost Reduction/Increase: There would be no cost impact; the staff understands that HHS-certified laboratories are currently retaining the original forms as intended by the current rule.

Backfit Rule Considerations: This is a clarification of existing requirements that would make explicit the disposition of the original custody and control form.

The CRGR charter stipulates that new or revised information collection and reporting requirements are not considered to be backfits.

***Staff Conclusion:* This revision is not a backfit because it is an information collection and reporting requirement. In addition, this revision is not a backfit because it clarifies, but does not change, a current requirement.**

Section 2.7(i) of Appendix A: Specimens associated with subversion to be placed in long-term storage

Revision: Section 2.7(i) [section 2.7(h) in the current rule] of Appendix A would be revised to specify that specimens associated with adulteration or dilution be placed in long-term storage.

Purpose: Section 2.7(h) of Appendix A currently requires HHS-certified laboratories to retain all specimens that have been confirmed positive in long-term storage for at least one year. Part of the purpose of retention of these specimens is to preserve evidence, if needed, for use at a proceeding challenging employment actions based on these specimens' test results. A revision to this section would add specimens that have been adulterated or diluted to those that must be retained. This revision reflects the fact that specimens that have been adulterated or diluted are indicators of FFD policy violations that must be retained as potential evidence, similar to specimens that have been confirmed positive for drugs.

Licensee Cost Reduction/Increase: Since the rule currently requires all confirmed positive specimens to be placed in long-term frozen storage for a minimum of one year and the industry-wide number of additional specimens that will have be retained is relatively small, this revision would create virtually no additional expense for licensees.

Backfit Rule Considerations: Both licensees and their employees should have the benefit of having all relevant evidence available in legal or administrative proceedings challenging FFD-related sanctions. Just as the rule requires that specimens confirmed as positive must be retained for this purpose, the staff also believes that specimens that have been adulterated or diluted be retained as potential evidence. This revision will affect only a relatively small number of specimens and result in virtually no additional expense for licensees.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would ensure that needed evidence related to sanctions imposed by licensees is retained for potential future use in proceedings challenging those actions.**

Section 2.7(j) of Appendix A: Retesting of adulterated or diluted specimens need only confirm specimen not valid

Revision: Section 2.7(j) would be revised to specify that retesting of adulterated or diluted specimens need only substantiate the information that the MRO used to make the original determination of adulteration or dilution..

Purpose: Section 2.7(j) of Appendix A currently indicates, due to specimen degradation, retesting need only confirm the presence of the drug's metabolite (i.e., cut-off levels do not apply). Section 2.7(j) would be revised to similarly provide that the retesting of specimens that have been adulterated or diluted need only substantiate the information that the MRO used to make the original determination rather than having to meet a quantitative criterion such as a cut-off level.

Licensee Cost Reduction/Increase: No cost impact.

Backfit Rule Considerations: This revision would have no cost impact on licensees, and is a worthwhile change because it would prevent unjustified reversals of test results..

***Staff Conclusion:* This revision is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would prevent unjustified reversals of test results.**

NEW: Section 2.7(k) of Appendix A: Extend time for forwarding split specimens for testing

Revision: Section 2.7(j) of Appendix A [section 2.7(k) in the revised rule] currently allows licensee employees to request that their split specimens be tested at another HHS-certified laboratory that did not test their primary specimen. This additional testing is used for purposes of appealing confirmed positive results from testing of primary specimens. This section currently requires licensees to send the split specimen to the second HHS-certified laboratory on the same day that the employee asks that the split specimen be tested. This section would be revised to give licensees up to three days to send the specimens.

Purpose: The staff is proposing this revision in response to NEI's request. It recognizes the fact that most licensees store split specimens at their HHS-certified laboratory, not at their on-site specimen collection facility. To have a split specimen forwarded to another laboratory for testing, the licensee must first contact its HHS-certified laboratory and

make the request. The laboratory staff then must retrieve the specimen and pack it securely for transportation before mailing it. This process normally takes longer than one day to accomplish and three days appears to be a reasonable period.

Licensee Cost Reduction/Increase: This revision should produce a small, unquantified reduction in burden.

Backfit Rule Considerations: This revision would relax current requirements by giving licensees three days rather than one day to forward split specimens for testing.

***Staff Conclusion:* This revision is not a backfit because it is a permissive relaxation of a current requirement.**

Section 2.7(m) of Appendix A: HHS-certified laboratories must have blood analysis capabilities

Revision: Section 2.7(m) would be revised to clarify that HHS-certified laboratories must have the capability to analyze whole blood for alcohol content.

Purpose: Section 2.7(k) of Appendix A [section 2.7(l) in the revised rule] currently requires that the HHS-certified laboratories be capable of testing whole blood, and that they be able to "perform confirmatory tests for alcohol." Section 4.1(b) of Appendix A currently requires licensees to use only those HHS-certified laboratories that agree to analyze blood specimens for alcohol. The wording of section 2.7(m) of the revised rule would be clarified regarding the need for HHS-certified laboratories to have the capability to analyze whole blood for alcohol content. This is not a new requirement; this revision to section 2.7(m) only makes this long-standing requirement explicit.

Licensee Cost Reduction/Increase: No cost impact.

Backfit Rule Considerations: This revision clarifies a current requirement and creates no cost impact on licensees.

***Staff Conclusion:* This revision is not a backfit because it clarifies, but does not change, a current requirement.**

Section 2.7(n) of Appendix A: Specify that licensee contracts with HHS-certified laboratories will assure that copies of records are available to licensees and NRC inspectors

Revision: Section 2.7(n) [section 2.7(m) in the current rule] of Appendix A would be revised by repeating the language from section 26.70(b)(2) (discussed above in Group IIIB) to assure that licensee contracts with HHS-certified laboratories require that licensees and NRC inspectors be able to copy and take away records and other pertinent documents.

Purpose: This is a conforming change to the revision of section 26.70(b)(2).

Licensee Cost Reduction/Increase: This revision would have no cost impact, as it is a change to conform with the proposed revision to section 26.70(b)(2). The costs associated with that revision are already accounted for in the primary discussion of this section.

Backfit Rule Considerations: This revision would reiterate the requirement from section 26.70(b)(2) and would not impose any new burden.

***Staff Conclusion:* This revision is an administrative change.**

Section 2.7(p) of Appendix A: Calibration standards (for calibrating equipment used to test for alcohol and screen for drugs) must be current and valid

Revision: Section 2.7(p) of Appendix A would be revised to specify that calibration standards (for calibrating equipment used to test for alcohol and screen for drugs) must be current and valid.

Purpose: Section 2.7(o) of Appendix A [section 2.7(p) in the revised rule] currently requires that labels for standards and controls contain an expiration date. Although not explicitly stated, the requirement was intended to also prohibit the use of such materials after their expiration date. A revision to section 2.7(p) would make explicit the implicit requirement that all standards and controls used to calibrate alcohol breath analysis equipment and equipment used at licensees' testing facilities for conducting screening tests must be current and valid for their purpose. Licensees have informed the staff that they have used out-of-date calibration standards for alcohol breath analysis. The staff is also aware of some instances of the deliberate use of expired calibration standards.

Licensee Cost Reduction/Increase: There may be some incremental increase in costs for licensees that use out-of-date/expired standards and controls, since they would have to purchase fresh, valid standards and controls. However, most licensees do not use out-of-date/expired calibration standards and controls and as a practical matter there will be little or no cost impact.

Backfit Rule Considerations: Section 2.7(o) of Appendix A currently requires that labels for standards and controls contain an expiration date. In addition, section 2.8(a) of Appendix A currently requires that licensees have a quality assurance program that includes validation of testing procedures, that known (i.e., current, valid) standards be used in the testing process [section 2.8(c)], and that standards and controls have an expiration date (i.e., useful life) [section 2.7(o)]. Based upon these requirements, it would seem manifest that only valid, in-date standards and controls are utilized in the FFD program. However, since licensees have occasionally used expired calibration standards, sometimes deliberately (or substantiated allegations), this change is needed to ensure compliance.

***Staff Conclusion:* This revision fits within the Backfit Rule's compliance exception.**

Section 2.7(p) of Appendix A: Two-year retention period for laboratory procedure manuals after end of contract with licensee

Revision: Section 2.7(p) would be revised to specify a two-year retention period for HHS-certified laboratory procedure manuals after the end of a contract with a licensee.

Purpose: Section 2.7(o) of Appendix A [section 2.7(p) in the revised rule] currently requires laboratories and licensees' testing facilities to maintain a current procedure manual and to retain superseded material for at least 3 years. A revision to section 2.7(p)(1) would require HHS-certified laboratories to retain a copy of their latest procedure manual as a record until at least two years after their contracts with licensees expire. Having the procedure manual available for that period will make it more likely that appeals of test results that may occur after expiration of contracts can be handled expeditiously.

Licensee Cost Reduction/Increase: There would be no cost impact, since HHS-certified laboratories are already required to maintain manuals as a record for three years after they have been superseded. The new requirement would allow the HHS certified laboratory to discard the manuals after two years, rather than three years as the current rule allows, if the HHS-certified laboratory's contract with the licensee ends.

Backfit Rule Considerations: This revision is a permissive relaxation to a current recordkeeping requirement. The CRGR charter stipulates that new or revised information collection and reporting requirements are not considered to be backfits.

Staff Conclusion: This revision is not a backfit because it is an information collection and reporting requirement. It also is a permissive relaxation of a current requirement.

Section 2.7(p) of Appendix A: Licensee to retain latest testing procedure manual until it is no longer performing on-site testing

Revision: This revision to section 2.7(p) [section 2.7(o) in the current rule] of Appendix A would additionally specify that any licensee performing on-site testing is to retain the latest testing procedure manual until the licensee is no longer performing on-site testing.

Purpose: Section 2.7(o)(1) of Appendix A currently requires laboratories and licensees' testing facilities to maintain a current procedure manual and to retain superseded material for 3 years. This revision would clarify that the licensee is required to maintain a current copy of its testing procedures manual as long as the licensee is conducting on-site testing.

Licensee Cost Reduction/Increase: No cost impact.

Backfit Rule Considerations: This revision clarifies existing requirements and would have no cost impact.

Staff Conclusion: This revision is not a backfit because it clarifies, but does not change, a current requirement.

Sections 2.8(a), (b), (c), (e), and (f) of Appendix A: Minor clarifying and conforming edits

Revision: Revisions would include using the term "screening test" instead of "initial test" and "specimen" instead of "sample".

Purpose: These changes are made to increase consistency in rule language.

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: These are minor administrative edits.

Staff Conclusion: This revision is not a backfit because it is an administrative change.

Section 2.8(b) of Appendix A: Laboratory results on blind performance specimens must be evaluated and appropriate corrective actions taken

Revision: Section 2.8(b) would be revised to specify that the results of laboratory testing on blind performance specimens must be evaluated and appropriate corrective actions taken.

Purpose: Section 2.8(b) of Appendix A, in setting forth quality control measures for on-site testing, currently requires licensees to process (test) blind performance specimens and submit a sampling of specimens screened as negative on site to the HHS-certified laboratory. This revision to section 2.8(b) would explicitly require that licensees evaluate the results they receive from their HHS-certified laboratories regarding specimens tested for quality control purposes (i.e., compare the on-site testing results to the laboratory testing results) and take appropriate corrective action to respond to those results.

Licensee Cost Reduction/Increase: There would be some incremental cost impact, since there are a few licensees who do not consistently evaluate the results of blind performance specimen tests.

Backfit Rule Considerations: Although the current rule does not explicitly require evaluating the results of blind performance test specimens and taking corrective action, the fundamental nature of blind performance tests, which is explicitly required by section 2.8(b), is of quality assurance and quality control (QA/QC), i.e., to evaluate the efficacy of the testing process and take corrective action. Section 2.8 itself is entitled, "Quality Assurance and Quality Control." Imposing a regulatory requirement to perform a QA/QC activity, but not requiring an evaluation of the results and appropriate corrective action would be irrational and inconsistent with achieving the agency's intent when it promulgated the requirement.

Staff Conclusion: This revision fits within the Backfit Rule's compliance exception. Alternatively, it can be viewed as a worthwhile change that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would ensure that licensees evaluate the results of quality control measures and take

appropriate action to correct detected problems, consistent with the concept of QA/QC.

Section 2.8(e) of Appendix A: Change the proportion of blank and positive blind performance test specimens

Revision: This revision would change the proportion of blank and positive blind performance test specimens.

Purpose: Section 2.8(e)(2) of Appendix A currently requires licensees to submit blind performance test specimens to their HHS-certified laboratories for purposes of quality assurance and quality control. Section 2.8(e)(3) currently requires that 80 percent of these specimens be blank and the remaining 20 percent be positive for one or more of the drugs for which the licensee is testing. A revision to this section evens the percentages for both blind and spiked specimens at 50 percent. This change has been made in response to a related revision of section 2.8(e)(2) which reduces the total number of blind performance test specimens that licensees have to submit to their HHS-certified laboratories. Increasing the percentage of positive blind performance test specimens that must be submitted would help offset the reduction in the total number of blind performance test specimens and would assure that an adequate number of positive blind specimens are submitted for quality control.

Licensee Cost Reduction/Increase: This revision is expected to result in no cost increases for licensees. In fact, this revision supports another change to this section that reduces the total number of blind specimens—a net decrease in licensee burden (see Group I, above).

Backfit Rule Considerations: This revision is part of a permissive relaxation in burden. If licensees continued to submit blind performance test specimens with the proportions required under the original rule, they would submit two spiked specimens for every 100 real specimens. Under this proposed revision, they will be able to submit on average only 1.5 spiked specimens for every 100 real specimens. While they will be able to submit blind performance test specimens in the currently required proportions if they so choose, using the proportions that are being proposed will result in having to send fewer blind performance specimens and result in small savings.

***Staff Conclusion:* This revision is not a backfit because it is part of a set of changes which, considered together, constitute a permissive relaxation of current requirements.**

Section 2.8(e) of Appendix A: Assure regularity of submission of blind test specimens

Revision: This revision would further assure regularity of submission of blind test specimens.

Purpose: A revision to section 2.8(e)(2) of Appendix A would require licensees to attempt to submit blind performance test specimens at a frequency that corresponds with the submission frequency of their specimens. This is consistent with the original intent of both the NRC and HHS. The purpose of this revision is to avoid having licensees submit all or most of their blind performance test specimens at one time, a situation which tends to decrease the quality assurance value of blind performance testing.

Licensee Cost Reduction/Increase: This revision is expected to result in no cost increases for licensees.

Backfit Rule Considerations: This revision would clarify the Commission's original implicit intent that blind performance specimens be submitted with regular specimens and not separately. For example, the current section 2.8(a) requires that quality control measures be implemented to monitor the conduct of the testing process, 2.8(b) requires a "sampling of specimens" from each test run conducted on site to be forwarded to the HHS-certified laboratories along with blind specimens, 2.8(c) and (d) require standards and quality controls to be included in each run of specimens, and 2.8(e)(3) requires the distribution of the drugs to be tested in the positive blind performance specimens be in approximately equal frequency of challenge. HHS has emphasized to the NRC staff the importance to these quality assurance/quality control measures that there be an even flow of blind perform test specimens.

NEI requested that the phrase "approximately equal frequencies of challenge" in the current section 2.8 (e)(3) be changed. This phrase is part of the currently existing requirement that blind performance test specimens positive for one or more drugs are to be submitted to HHS-certified laboratories in a way that creates approximately equal frequencies of challenge for all drugs. NEI asked the Commission to clarify this phrase so that licensees would not have to create new tracking systems to determine "frequency of challenge." NEI's concern is associated with current wording that the NRC is not proposing to change. (This NRC rule wording in section 2.8(e)(3) of Appendix A is identical to that creating a similar requirement in section 2.5(d)(3) of the HHS Mandatory Guidelines.) There cannot, therefore, be any new need for licensees to establish tracking systems to comply with this requirement. No backfit issue is raised by this NEI recommendation.

Staff Conclusion: This revision is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would ensure that licensees provide adequate quality assurance/control measures for the testing process. It would also ensure compliance with the current implicit requirement in section 2.8(b) of Appendix A that blind specimens accompany regular specimens being sent to the laboratory.

Section 2.8(e) of Appendix A: Adulterate or dilute and spike some blind performance specimens

Revision: Section 2.8(e)(3) of Appendix A would be revised to require that 10 percent of the positive blind performance test specimens that licensees submit to their HHS-certified laboratories be appropriately adulterated or diluted and spiked to between 60 and 80 percent of the NRC's screening cut-off values or of any lower cut-off values established by the licensee.

Purpose: This revision would enable licensees to challenge their laboratories' ability to determine specimen validity which is now required by the new section 2.7(e).

Section 2.8(e) currently requires the use of blind performance test specimens in the quality assurance program. The submission of blind performance test specimens that have been adulterated or diluted and spiked to a concentration level less than established screening cut-off values is an important quality control measure to assure laboratory capability to determine specimen validity and perform special processing. Without this quality control measure, there would be no assurance that the specimen validity determination requirements of section 2.7(e) of Appendix A would be met with respect to adulteration and dilution (see discussion of section 2.7(e) in Group I). Use of blind performance test specimens at the levels which would be mandated by this proposed revision will provide continuing assurance that HHS-certified laboratories are effectively and accurately testing specimens for validity.

Licensee Cost Reduction/Increase: The reduction in the number of blind specimens required by section 2.8(e)(5) of Appendix A (discussed in Group I) would reduce licensees' costs; this requirement to adulterate or dilute and spike blind performance specimens would reduce this savings by only a minimal amount. Therefore, this revision, when considered with its related change, would not create an overall increase in burden.

Backfit Rule Considerations: This requirement regarding submission of adulterated or diluted blind test specimens is being made in conjunction with companion revisions to

section 2.8(e)(2). A revision to that section has substantially reduced the required total number of blind performance specimens that licensees must submit to their HHS-certified laboratories as part of their overall quality assurance and quality control programs. The requirement that blind test specimens be adulterated or diluted and spiked to some percentage of the NRC's screening cut-off values is necessary to maintain the integrity of the blind test specimen program in light of the companion reduction in the number of blind specimens being submitted.

NEI recommended deletion of the proposed requirement that FFD programs submit adulterated or diluted blind specimens that are spiked to 60 percent of the drug testing cut-off levels. NEI considered this to be too prescriptive and unnecessary to ensure HHS-certified laboratory capability.

The NRC staff has made revisions to this section that would give licensees flexibility in determining the percentage of the screening cut-off level at which positive blind specimens must be spiked. This revision would allow each licensee to determine its own appropriate level of spiking depending on the lowest screening cut-off level that its HHS-certified laboratory is capable of performing. The staff has been informed that such spiked test specimens can be made easily commercially available.

As discussed in Group I above, HHS has recently published NLCP Program Document #35 that sets forth standards for specimen validity testing by HHS-certified laboratories similar to that being proposed in section 2.7(e). HHS has notified the NRC staff that it is also developing quality assurance measures that will assure that the laboratories are capable of accurately conducting validity testing. The fact that HHS recognizes the need for such quality assurance measures demonstrates the need for such measures in the FFD rule.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it is an important quality assurance measure relating to validity of the testing process.**

Section 2.8(e) of Appendix A: Specify that initial 90-day period for blind performance testing rate applies to all new contracts with HHS-certified laboratories

Revision: Section 2.8(e)(2) of Appendix A would be revised to clarify that the current requirements in this section for intensified blind performance testing rate (currently 50 percent of the total number of samples submitted, but 20 percent under the proposed change to this section discussed in Group I) for the initial 90-day period of any new testing program applies to all new contracts with HHS-certified laboratories.

Purpose: Section 2.8(e)(2) currently requires intensified blind performance testing for "the *initial* 90-day period of any *new* drug testing program" (emphasis added). When a licensee ends a contractual relationship with one HHS-certified laboratory and begins a new contractual relationship with another HHS-certified laboratory, but the testing program remains the same, Section 2.8(e)(2) would not require intensified blind performance testing during the initial 90 days of the new contract with the second HHS-certified laboratory. To address this problem, section 2.8(e)(2) would be changed to read "the *initial* 90-day period of any *contract* with an HHS-certified laboratory" (not including rewritten or renewed contracts). This will assure that intensified blind performance testing is performed during the initial 90 days of a new contractual relationship with a HHS-certified laboratory. The requirements for intensified testing would not be applied to rewritten or renewed contracts with the current HHS-certified laboratory.

Licensee Cost Reduction/Increase: In the absence of this change, licensees currently are required to have a blind performance testing rate of 10 percent. Thus, the proposed intensified testing for the initial 90 days of a new contract would represent a 10 percent increase in required testing. This is estimated to cost less than \$2,000 per licensee each time a licensee changes contracts with an HHS-certified laboratory. The frequency of licensees changing their contracts with HHS-certified laboratories is not known with precision but is believed to be infrequent.

Backfit Rule Considerations: The current rule requires intensified blind performance testing as an important QA/QC measure whenever a new test program is initiated. The staff believes that the need to verify the validity of newly-implemented testing programs is paralleled by the need to verify the implementation of an existing program by a new HHS-certified laboratory. The possibility of error attributable to "start-up" exists not just when a new program is implemented, but also when a newly-contracted laboratory must learn and implement a new (to that laboratory) program. Furthermore, each HHS-certified laboratory has unique aspects for implementing the testing program which are not part of the licensee's description of the testing program. Thus, even if the "testing program"

remains unchanged, the HHS-certified laboratory processes for implementing the licensee's testing program changes. These laboratory-specific aspects would also be assessed by the intensified testing. The revision will provide the licensee with the capability to assess the performance of a HHS-certified laboratory whenever the licensee begins a new contractual relationship with an HHS-certified laboratory.

Staff Conclusion: This is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would provide an important quality assurance measure relating to the validity of the testing conducted by HHS-certified laboratories that have established a new contractual relationship with a licensee.

Section 2.8(f) of Appendix A: Investigation of testing process errors and inclusion of report of action taken

Revision: Section 2.8(e)(4) [which is redesignated as section 2.8(f)(1)] of Appendix A would be revised to clarify that licensees must investigate any testing errors or unsatisfactory performance identified throughout the testing process or during the appeals process.

Purpose: Paragraph 2.8(e) of Appendix A is entitled, "Licensee Blind Performance Test Procedures." Subparagraph (e)(4) of the rule currently states that licensees must investigate (or refer to HHS for investigation) "any unsatisfactory performance testing result and, based on this investigation the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory...". When adopting the current rule, the NRC intended (but did not explicitly document) that testing or process errors discovered in any part of the Part 26 testing program, not just blind performance testing, would be investigated. However, because paragraph 2.8(e) refers only to blind performance testing, the provision could be read as applying only to blind performance testing rather than all parts of the Part 26 testing program.

The revision would also provide a permissive relaxation to the reporting requirements. The current rule requires the licensee to make a record of the investigative findings and the corrective action taken and then submit that document to the NRC as a report. The revision would permit licensees to prepare an abbreviated report of the incident and action taken or planned.

Licensee Cost Reduction/Increase: The first part of the revision will result in a very small incremental increase in cost, based upon the staff's understanding that there are very few testing or process errors in the entire nuclear industry (approximately 2-4 annually for all licensees). The second part of the revision is a permissive relaxation which could result in some unquantified cost savings.

Backfit Rule Considerations: The first part of the revision will assure that any adverse test or process errors which are discovered are appropriately investigated by licensees and corrective action implemented as necessary. The second part of the revision, which permits an abbreviated report, constitutes a change to an information collection requirement. The CRGR Charter states that new or revised information collection and reporting requirements are not considered to be backfits.

***Staff Conclusion:* The revision concerning the investigation of testing process errors is a worthwhile revision that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would ensure that all testing process errors are investigated and corrective action taken, as appropriate. The revision concerning an abbreviated report is not a backfit because: (a) it is an information collection and reporting requirement, and (b) it is a permissive relaxation of a current requirement.**

Section 2.8(f) of Appendix A: All false positive errors must be reported to NRC

Revision: Section 2.8(f)(2) [section 2.8(e)(5) in the current rule] of Appendix A would be revised so that, where there is a false positive error on a "regular specimen" (i.e., an actual specimen from an individual) that the licensee report the error to the NRC and require the HHS-certified laboratory to take corrective action.

Purpose: Section 2.8(e)(5) currently requires that where there is a false positive error on a *blind performance test specimen*, the licensee promptly report the error to the NRC and require the HHS-certified laboratory to take corrective action. However, there is no analogous requirement for false positive errors on an actual specimen taken from a individual being tested under the FFD program. Because of the potentially significant adverse impact on the individual being tested, as well as a significant adverse impact on program acceptance by the general licensee, contractor and vendor workforce, the staff believes that the FFD rule should clearly require the reporting, investigation, and corrective action concerning a false positive result in a test of an employee's specimen, as well as a blind performance test specimen.

Licensee Cost Reduction/Increase: This revision is likely to result in a minimal incremental increase in cost to licensees. Since the implementation of the rule in 1990, only 2 false positives on actual specimens have been reported (see Appendix D to NUREG/CR-5758, Volume 2).

Backfit Rule Considerations: Section 2.8(e)(5) [section 2.8(f)(2) in the revised rule] currently requires that a false positive error on a blind performance test specimen be promptly reported to the NRC and corrective action be taken by the laboratory. Failure to investigate and correct false positives in actual specimens would have an adverse impact upon the tested individual, unless the appeal process was successful in overturning the incorrect licensee decision to deny unescorted access (or take other action required under this part). Moreover, were the general workforce of the licensee and its contractors and vendors to discover that errors in actual samples were not being corrected despite the licensee's knowledge, the FFD testing program would lose its credibility and acceptability to those being tested. The Commission stated, as part of this proposed rulemaking at 61 FR 21107; May 9, 1996, that one of the purposes of specific measures required by the rule is the intent to protect workers against unwarranted damage to their careers and that quality controls to assure accurate, valid, and dependable test results would bolster FFD program credibility and acceptance among workers. In a report resulting from an extensive review of the literature on organizational influences on deterrence, it was concluded that the workplace culture should assist in deterring drug use and behaviors that are legitimately perceived as posing a health and safety risk (see 5.3.9 of NUREG/CR-6470). To assure that the FFD testing is credible and the workplace culture promotes the protection of public health and safety, the NRC should be aware of false positives of actual specimens so that the NRC can monitor the licensees' and HHS-certified laboratory's response and corrective action. Therefore, the staff believes that the NRC should be informed of such occurrences.

***Staff Conclusion:* This revision is a worthwhile change that the staff recommends be considered for adoption as an exception to the Backfit Rule because it would ensure that false positive test results on an actual specimen would be properly addressed. The revision with respect to reporting to the NRC is not a backfit because it is an information collection and reporting requirement.**

Section 2.9(a) of Appendix A: Minor conforming edits

Revision: These revisions would be minor edits, changing words, but not the meaning of the rule.

Purpose: To increase consistency in rule language.

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: These are minor administrative edits.

Staff Conclusion: This revision is not subject to backfit requirements because it is an administrative change.

Sections 2.9(b), (c), (d), (e), and (f) of Appendix A: Clarifying and conforming changes to MRO duties for reporting and review of results

Revision: These revisions would add language to clarify the role of the MRO in the FFD program. Additional language to provide guidance would be added to respond to public comments, including revisions to section 2.9(c) of Appendix A to expand coverage to all FFD policy violations, to authorize MROs to declare an FFD policy violation when the employee does not report to the MRO after notification to report, and to allow the MRO to rescind a declaration of an FFD policy violation if the employee reports to the MRO after being unavailable for an extended period and has a legitimate explanation for the positive test result and failure to report promptly. The revision to section 2.9(b) involving conflict of interest standards is discussed under Group IA.

Purpose: The revision to section 2.9(b) would assure that someone with the appropriate expertise advises management in relevant areas. This suggests item 5.8 of NUREG-1385 which summarizes HHS' "Medical Review Officer Manual" in describing the MRO's duties are to address an assist management in the planning and oversight of the overall substance abuse program. Modifications to the revision to section 2.9(e) were made in response to public comment. Commenters requested guidance for handling situations in which employees who have a confirmed positive test results leave the employer or, for other reasons, do not report to the MRO for an interview to discuss the test result. Changes to section 2.9(c) would provide specifications for handling these situations consistent with provisions in the DOT Procedures for Transportation Workplace Drug Testing Programs. These changes would allow the MRO to verify a laboratory confirmed positive test result without having communicated directly with the employee when the person refuses to be interviewed by the MRO; cannot be contacted for 14 days or does not contact the MRO for 5 days after being contacted by the licensee. Another revision to section 2.9(c) would authorize the MRO, after a documented best-efforts attempt to contact the employee, to declare a laboratory confirmed positive test result to be an FFD policy violation without having interviewed the person. Provisions for overturning this

ruling would also be provided. In a related revision, section 2.9(c) would also be revised to expand its coverage concerning MRO verification of results from only positive test results to all FFD policy violations.

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: These revisions to section 2.9 of Appendix A clarify the role of the MRO and do not change current requirements or practices.

Staff Conclusion: These revisions are not backfits because they clarify, but do not change, current requirements.

Section 2.9(d) of Appendix A: Clarification of clinical evidence of abuse

Revision: This revision would clarify clinical evidence of abuse. This revision is related to a change to this section concerning evaluation of clinical evidence of the abuse of legal drugs discussed under Group IIB, above.

Purpose: Section 2.9(d) currently of Appendix A requires MROs to determine whether there is clinical evidence of workers' unauthorized use of opiates before verifying laboratory confirmed positive test results for opiates. The May 1996 proposed revisions included a change to this section that would have indicated that clinical evidence can include evidence of lack of reliability or trustworthiness on the part of workers.

Commenters requested guidance and argued convincingly that equating lack of reliability and trustworthiness to "clinical evidence" would not be a practical approach for verifying opiate abuse. It is understandable that lack of reliability or trustworthiness would be difficult criteria for MROs to apply, and this revision has been withdrawn.

Two other minor revisions to this section would clarify the types of clinical evidence that MROs can use to verify opiate positive test results. First, the staff is aware that some licensees have interpreted the examples of clinical evidence of abuse currently set forth in this section to be all inclusive. To make it clear that the examples of clinical signs of opiate abuse currently listed in this section are not to be the only types of evidence to be used to verify a laboratory confirmed positive test result, the words "but not limited to" would be added to this section. This would make it clear that MROs are to consider other types of clinical evidence beyond the examples listed in this section. The second change would be to add "admission of non-prescribed opiate use" to the list of examples. This

change would respond to questions from licensee FFD program staff as to whether such admissions are to be considered clinical evidence of opiate abuse.

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: The staff has decided to withdraw the revision concerning lack of reliability and trustworthiness, thus eliminating any backfit consideration for that change. Two minor revisions are made to clarify and provide guidance regarding the original intent of the rule in gathering and evaluating clinical signs of opiate abuse.

***Staff Conclusion:* This revision is not a backfit because it clarifies, but does not change, a current requirement.**

Sections 2.9(f) and (g) of Appendix A: Medical determination of fitness to perform duties defined

Revision: Section 2.9(f) would be revised so that, where the MRO determines that there is a legitimate medical explanation for a positive test result conducted under section 26.24(a) but there is nonetheless a potential risk to public health and safety of the individual being impaired, the MRO would be required to conduct a "medical determination of fitness." This term is a new term which is defined in section 26.3, and is discussed above in Group IIIB.

New section 2.9(g)(1) to Appendix A would require an MRO to perform a "medical determination of fitness" in the following cases: 1) where an alternative examination explains the test results but there is a basis for believing that impairment on duty could exist, 2) in the evaluation of all for-cause test results, 3) prior to making return-to-duty recommendations, 4) prior to granting unescorted access to the protected area when a record of a prior FFD violation exists, and 5) if a history of substance abuse is otherwise identified.

New section 2.9(g)(2) specifies that where the licensed physician or MRO determines that there is inconclusive evidence of a FFD policy violation but there is concern about the individual's fitness to perform, the results should not constitute a FFD policy violation, but that actions must be taken to assure that the individual's condition does not represent a threat to the workplace or public health and safety.

Purpose: Section 2.9(f) currently requires that the MRO determine whether there is a legitimate medical explanation for a positive test result, and that the substance identified was used in the manner and at the proper dosage prescribed. However, the section does

not require the MRO to determine whether the individual is fit for performing assigned duties despite the lack of a FFD policy violation. The proposed change would correct this problem by requiring the MRO to perform such a fitness evaluation.

New section (g)(1), by consolidating and reiterating in one place the circumstances (not intended to be exclusive) for which a medical determination of fitness must be performed would increase assurance that the determination is performed for circumstances where fitness may be questionable.

New section (g)(2) would assure that whenever there is reason to believe that a person may be unfit for duty despite the lack of a FFD policy violation, that the individual would be evaluated for fitness to assure that appropriate actions are taken to ensure that there is no threat to the workplace or to public health and safety. This section also assures that there would be no adverse FFD program impact to an individual who was determined unfit for duty but was not found to be in violation of a FFD policy.

Licensee Cost Reduction/Increase: There would be some incremental increase in cost associated with the need to perform additional medical determinations of fitness. The staff estimates that each medical determination of fitness would average a half hour in length, and that an additional ten determinations would be required as the result of these revisions, for a total of 5 hours. At \$135/hour for medical or MRO services, the total yearly cost per licensee would be \$675. For the entire industry of 74 sites, this would translate to approximately \$50,000/year.

Backfit Rule Considerations: Section 26.27(b) currently requires that a satisfactory medical assurance of the individual's fitness must be obtained before permitting the individual to be returned to duty.

***Staff Conclusion:* This is a worthwhile revision that the staff recommends be adopted as an exception to the Backfit Rule, because it would provide increased assurance that licensees will conduct appropriate medical evaluations to determine if an individual is unfit for assigned duties, despite the lack of a FFD evaluation, and would protect from adverse FFD program impacts those individuals who are identified as being unfit through these evaluations.**

Commission Determination: The Commission has decided, consistent with its decision with respect to §26.24(a)(3), not to adopt the Staff's recommendation with regard to a medical determination of fitness after a negative for-cause test.

Section 2.9(h) of Appendix A: Conforming language for extrapolation of BAC results between 0.02 and 0.04

Revision: Conforming language for extrapolation of BAC results between 0.02 and 0.04.

Purpose: The Commission's May 1996 proposed revisions included a new section 2.9(h) of Appendix A that provided guidance as to how licensees were to use back extrapolation when detecting an alcohol breath test result between 0.02 percent and 0.04 percent BAC. Because the staff has decided to withdraw the back extrapolation requirement, this new section is no longer necessary and has also been withdrawn. (But see discussion under section 26.24(h), Group IIIA, above.)

Licensee Cost Reduction/Increase: No cost impact.

Backfit Rule Considerations: The staff has decided to withdraw this revision thus eliminating any backfit consideration.

Staff Conclusion: Not applicable.

Section 2.9(h) of Appendix A: Minor clarifying edits

Revision: This revision to the current section 2.9(g) [section 2.9(h) in the revised rule] of Appendix A includes minor edits that change terms but not the meaning. [Note that this subsection has been changed from "(i)" in the 1996 proposed rule to "(h)" in the final rule.]

Purpose: These edits increase consistency in rule language, for example, "Medical Review Officer" is replaced with "MRO" and "sample" is replaced with "specimen."

Licensee Cost Reduction/Increase: No impact.

Backfit Rule Considerations: These are minor administrative edits.

Staff Conclusion: These revisions are not a backfit because they are administrative changes.

NEW: Section 4.1(c): Contracts must require implementation

Revision: A new section 4.1(c) would require that contracts between licensees (including their contractors) and the HHS-certified laboratories must require implementation of all obligations of Appendix A applicable to the laboratories.

Purpose: Because NRC regulations only apply to NRC licensees and do not include HHS-certified laboratories, this revision was recommended by OGC to ensure that there is a legal basis for requiring HHS-certified laboratories to comply with Appendix A.

Licensee Cost Reduction/Increase: There should be no cost impact. Licensee contracts require the HHS-certified laboratories to comply with Part 26. For any licensee or contractor that does not, it should be a simple change.

Backfit Rule Considerations: The revision does not require the licensee to change its procedures for conducting FFD matters. Rather, it requires that licensees' contracts with HHS-certified laboratories contain a provision to assure that the laboratories are contractually obligated to comply with Appendix A. This provides added assurance that HHS-certified laboratories will be in compliance with Appendix A.

***Staff Conclusion:* This revision is not a backfit because it is an administrative change. Also, it fits within the Backfit Rule's compliance exception.**

SUMMARY OF ADDITIONAL CHANGES DEVELOPED AFTER PUBLICATION OF PROPOSED RULE

Section 26.10(c)(3): FFD program must have performance objective of drug-free workplace, and a workplace free of the effects of such substances.

Revision: Section 25.10(c)(3) would be deleted.

Purpose: The terms, "drug-free workplace" and "workplace free from the effects of such substances" are ambiguous and could be read as prohibiting the valid onsite use of over-the-counter drugs and prescriptions drugs where there is no impact on fitness for duty, and the cut-off levels for these legal drugs are not exceeded. Furthermore, the Commission never intended the FFD program to address all drugs and did not establish cut-off levels for many drugs whose effects have no impact on fitness for duty. Since the two other performance objectives are clearly directed at assuring fitness for duty and detecting drugs that could have an adverse

impact on fitness, the Commission does not believe that the third performance objective in Section 26.10(c) is necessary.

Licensee Cost Reduction/Increase: No cost impact.

Backfit Rule Considerations: This change does not involve a backfit, inasmuch as it clarifies the appropriate scope of the Part 26 FFD program.

Staff Conclusion: This revision is an administrative matter and a clarification.

Summary of proposed changes that have been withdrawn

Twelve proposed revisions have been withdrawn by the Staff, as discussed in detail in the above analysis.

- 1) *Section 26.2(e): Clarify requirements during decommissioning*, discussed in Group IIB, page 59.
- 2) *Section 26.20(e)(1): Declaration of fitness to perform tasks assigned when contacted for call in*, discussed in Group IIIB, page 98.
- 3) *Section 26.24(a)(3): Clarify conditions that initiate for-cause tests*, discussed in Group IIIB, page 104. Note: only the revision pertaining to subversion is withdrawn.
- 4) *Section 26.24(h): Require back calculations for BACs between 0.02 and 0.04*, discussed in Group IIIA, page 78. Note: This was replaced by specific cutoff levels that varied over time.
- 5) *Section 26.27(a): Fitness history need not be obtained for those covered by other programs or who are absent for 30 days or less*, discussed in Group IIA, page 50.
- 6) *Section 26.27(b)(3) and (4): Minimum sanctions for positive test for alcohol or the use of alcohol within the protected area*, discussed in Group IIIA, page 80.
- 7) *Section 2.3(b) and 2.3 of Appendix A: Fitness-for-duty program personnel tested by independent personnel to the extent practicable and minor clarifying edits*, discussed in Group IIIB, page 125. Note: Only proposed change to section 2.3(4) concerning the testing of FFD program personnel has been withdrawn.
- 8) *Section 2.6 of Appendix A: Assure that training of licensee testing facility managers includes maintenance of chain-of-custody procedures*, discussed in Group IA, page 16.
- 9) *Section 2.7(h) of Appendix A: Reduce time for laboratories to report results*, discussed in Group IIB, page 72.
- 10) *Section 2.7(k) of Appendix A: Minimum time for requests by individuals to have split specimen tested at another HHS-certified laboratory*, discussed in Group IB, page 36. Note: Minimum of 72 hours replaced by “timely.”

- 11) *Section 2.9(e) of Appendix A: Minimum time for request by individual for reanalysis of original specimen added*, discussed in Group IB, page 39.
- 12) *Section 2.9(h) of Appendix A: Conforming language for extrapolation of BAC results between 0.02 and 0.04*, discussed in Group IIIB, page 150.

In addition, the Commission determined the following proposed revisions should be withdrawn:

- 13) *Sections 26.24 (a)(3) and 2.9(g) of Appendix A: Medical determination of fitness after a negative for-cause test*. Note: Only proposed changes to sections 26.24(a)(3) and 2.9(g) of Appendix A concerning a medical determination of fitness after a negative for-cause test have been withdrawn, discussed in Group IIA, page 54 and in Group IIIB, page 177, respectively.
- 14) *Section 2.4(g)(13) and (15) of Appendix A: More restrictive temperature range for an acceptable urine specimen*, discussed in Group IIIA, page 101.

SUMMARY OF WORTHWHILE CHANGES RECOMMENDED FOR ADOPTION AS EXCEPTIONS TO THE BACKFIT RULE

Thirty-six revisions were identified as worthwhile revisions that the staff recommends be considered for adoption as exceptions to the Backfit Rule, as discussed in detail in the above analysis. Eight are in Group IA, two in Group IB, two in Group IIA, one in Group IIB, four in Group IIIA, and nineteen in Group IIIB.

- 1) *Section 26.2(a)(4): FFD program personnel to be covered by FFD rule*, discussed in Group IIIB, page 91.
- 2) *Section 26.20(a): Off-site involvement with drugs, subversion of the testing process, and refusals to test added to policy statement*, discussed in Group IIIB, page 96. Note: this revision consists of three parts and only the one part requiring FFD policies to address off-site involvement of drugs is recommended to be considered a worthwhile change.
- 3) *Section 26.23(a)(2): Clarify that persons with a known (to the contractor or vendor) history of substance abuse must not receive assignments to the protected area without the knowledge and consent of the licensee*, discussed in Group IIIB, page 101.
- 4) *Section 26.24(a)(5): Clarify existing testing requirements for persons unavailable for testing for short periods and insure consistency with the access authorization program*, discussed in Group IIA, page 46. Note: this revision consists of three parts and only the one part concerning tests after extended absences is recommended to be considered a worthwhile change.
- 5) *Section 26.24(a)(5): Require return-to-duty testing after extended absences or denial of access*, discussed in Group IIIA, page 76. Note: this revision consists of two parts and only the one part concerning the testing of personnel returning to work after extended absences or after having been denied access under section 26.27(b) is recommended to be considered a worthwhile change.
- 6) *Section 26.24(f): MRO to report FFD policy violation in writing*, discussed in Group IA, page 7.
- 7) *Section 26.24(h): Require back calculations for BACs between 0.02 and 0.04*, discussed in Group IIIA, page 78.

- 8) *Section 26.25: Clarify that EAPs must be designed to achieve early intervention and must assure confidentiality*, discussed in Group IIIB, page 109.
- 9) *Section 26.27(a): Certain aspects of fitness history to be limited to 5 years*, discussed in Group IIB, page 64.
- 10) *Section 26.27(b)(1), (3), and (5): Clarification of requirements with respect to access denial, removal, and return to service*, discussed in Group IIIB, page 110. Note: This revision consists of two parts, and only the revision to 26.27(b)(1) concerning who can make return-to-duty decisions is recommended as a worthwhile change.
- 11) *Section 26.27(b)(3): People suspended must still be covered by behavioral observation, chemical testing, and sanctions for violations*, discussed in Group IIIB, page 113.
- 12) *Section 26.27(c): Clarify that acts of subversion must be violations of policy and result in denial of unescorted access for 3 years and that the specific cause for removal must be provided in response to an inquiry*, discussed in Group IIIB, page 114.
- 13) *Section 26.28: Clarify that the appeals process must be objective and conducted by persons not associated with the FFD program*, discussed in Group IIIB, page 115.
- 14) *Section 26.29(c): Assure provision of copies of records to individuals upon written request*, discussed in Group IIIA, page 84.
- 15) *Section 2.4(f)(1) and 2.4(f) of Appendix A: Current or previous specimen that fails to meet normal standards constitutes a reason to require observed testing and minor clarifying changes*, discussed in Group IIIB, page 126.
- 16) *Section 2.4(g)(4) of Appendix A: Eliminate requirement that tester request list of medications prior to specimen collection*, discussed in Group IA, page 11.
- 17) *Section 2.4(g)(11) of Appendix A: Require partial specimens to be shipped separately and not combined*, discussed in Group IB, page 26.
- 18) *Section 2.7(c) of Appendix A: Require chilling or testing within one day of arrival at HHS-certified laboratory*, discussed in Group IIIB, page 130.

- 19) *Section 2.7(e) of Appendix A: Conduct special processing of questionable specimens at HHS-certified laboratory (formerly: Test questionable specimens to limit of detection),* discussed in Group IIA, page 56.
- 20) *Section 2.7(e): Require on-site testers to determine validity of specimens on site,* discussed in Group IIIA, page 89.
- 21) *Section 2.7(f) of Appendix A: Prohibit non-instrumented testing devices,* discussed in Group IA, page 18.
- 22) *Section 2.7(g) of Appendix A: Modify the criteria for determining that a specimen is positive for amphetamines,* discussed in Group IA, page 19.
- 23) *Section 2.7(g) of Appendix A: Require testing for d and l isomers of amphetamines,* discussed in Group IA, page 20.
- 24) *Section 2.7(i) of Appendix A: Specimens associated with subversion to be placed in long-term storage,* discussed in Group IIIB, page 134.
- 25) *Section 2.7(j) of Appendix A: Retesting of adulterated or diluted specimens need only confirm specimen not valid,* discussed in Group IIIB, page 135.
- 26) *Section 2.7(k) of Appendix A: Minimum time for requests by individuals to have split specimen tested at another HHS-certified laboratory,* discussed in Group IB, page 36.
- 27) *Section 2.7(p) of Appendix A: Laboratory shall not have a conflict of interest with licensee's MRO,* discussed in Group IA, page 21.
- 28) *Section 2.8(b) of Appendix A: Laboratory results on blind performance specimens must be evaluated and appropriate corrective actions taken,* discussed in Group IIIB, page 139.
- 29) *Section 2.8(e) of Appendix A: Require that blind quality control materials meet standards for preparation, certification, and stability,* discussed in Group IA, page 22.
- 30) *Section 2.8(e) of Appendix A: Assure regularity of submission of blind test specimens,* discussed in Group IIIB, page 141.
- 31) *Section 2.8(e) of Appendix A: Adulterate or dilute and spike some blind performance specimens,* discussed in Group IIIB, page 142.

- 32) *Section 2.8(e) of Appendix A: Specify that initial 90-day period for blind performance testing rate applies to all new contracts with HHS-certified laboratories*, discussed in Group IIIB, page 143.
- 33) *Section 2.8(f) of Appendix A: Investigation of testing process errors and inclusion of report of action taken*, discussed in Group IIIB, page 144. Note: this revision consists of two parts and only the one part requiring licensees to investigate testing process errors is recommended to be considered a worthwhile change.
- 34) *Section 2.8(f) of Appendix A: All false positive errors must be reported to NRC*, discussed in Group IIIB, page 145. Note: this revision consists of two parts and only the one part requiring the licensee to require the HHS-certified laboratory to take corrective action is recommended to be considered a worthwhile change.
- 35) *Section 2.9(b) of Appendix A: MROs shall not have a conflict of interest with certified laboratories*, discussed in Group IA, page 23.
- 36) *Sections 2.9(f) and (g) of Appendix A: Medical determination of fitness to perform duties defined*, discussed in Group IIIB, page 149.

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APPENDIX A: RESOLUTION OF CRGR RECOMMENDATIONS

The ACRS and the CRGR recommend issuance of the proposed final revisions to 10 CFR Part 26, as described in the proposed Federal Register notice (Attachment A). The CRGR concluded that the following four revisions to the FFD rule should not be compliance exceptions:

- §2.7(f) of Appendix A to 10 CFR Part 26 (conforming the marijuana screening cutoff level);
- §2.7(e) of Appendix A to 10 CFR Part 26 (determination of specimen validity);
- §26.24(e) (limit time between notification and collection); and
- §26.22(c) (complete training of contractor supervisors not later than 10 days of initial supervisor assignment).

Rather than compliance exception, CRGR recommended that §§ 2.7(f) of Appendix A, 26.24(e) and 26.22(c) be categorized as backfits and that §2.7(e) of Appendix A be categorized as either a backfit or worthwhile change. CRGR also suggested that the §26.22(c) change revert to the original language or that alternative language be substituted to read that training for contract supervisors should be completed as soon as feasible. Notwithstanding, NRR and OGC conclude that the compliance exception is the appropriate application of the Backfit Rule in each of these cases and is legally defensible. For each change, NRR's and OGC's rationale for the compliance exception categorizations are as follows:

- (1) §2.7(f) of Appendix A: The Commission's intent, as discussed in the 1989 FFD rule SRM, has always been that the cut-off screening level for marijuana be set at the lowest level that would yield reliable results. When the rule went into effect nearly 10 years ago, 100 nanograms was the level that technology could support to achieve reliable results. Technology in urinalysis has advanced and can now reliably support drug screening at the proposed cut-off level of 50 nanograms. This change conforms to the Commission's original intent.
- (2) §2.7(e) of Appendix A: The rule has always required licensees to verify the validity of specimens to prevent subversive activities such as adulteration or hydration. However, the language was fragmented and not always clear. This clarifies existing requirements and consolidates them in one section of the rule.
- (3) §26.24.(e): There has always been a general requirement in the rule to limit a selected individual's opportunity to compromise a specimen. However, this

requirement was not specifically stated in the rule and, therefore, was not consistently applied by all licensees. This change clearly states the requirements of the existing rule.

- (4) §26.22(c): The Commission has always intended for supervisors with behavioral observation responsibilities to be trained in a timely manner. However, the 3-month training window is vulnerable to contractor personnel who may be at a licensed facility for less than 3 months, due to shortened facility outages, and, therefore, may never receive the required training. This vulnerability would still exist if the training window were changed to as soon as feasible. It would also continue to exist if §26.22(c) were revised to eliminate the proposed requirement that supervisors employed by contractors be trained in their supervisory responsibilities “within 10 days after the first assignment to onsite supervisory duties” and return to current wording, which is “within 3 months after initial supervisory assignment.” The 10 days is based on data submitted by licensees that show higher rates of positive test results for contractors (approximately double that for licensee employees); therefore, timely training of responsibilities in implementing the FFD rule is particularly important for supervisors employed by contractors. Furthermore, this revision would prevent abuses that resulted in contractor personnel being supervised by people who had never been trained in FFD program requirements. The change is being made to ensure compliance with existing requirements.

NRR and OGC conclude that the compliance exception is an appropriate application of the Backfit Rule in each of these cases, and is legally defensible. As with all other revisions to 10 CFR Part 26 in this rulemaking package, these are needed changes and are well justified regardless of how they are classified under the Backfit Rule.

ATTACHMENT G

**FORM TO GAO:
SUBMISSION OF FEDERAL RULES
UNDER THE CONGRESSIONAL REVIEW ACT**

	<u>Yes</u>	<u>No</u>	<u>N/A</u>
1. With respect to this rule, did your agency prepare an analysis of costs and benefits?	M	F	F
2. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5U.S.C.§605 (b)?	M	F	F
2. Prepare a final Regulatory Flexibility Analysis under 5U.S.C.§604 (a)?	F	M	F
C. With respect to this rule, did your agency prepare a written statement under §202 of the Unfunded Mandates Reform Act of 1995?	F	F	M
D. With respect to this rule, did your agency prepare an environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Act (NEPA)?	F	M	F
E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?	M	F	F
F. Did you discuss any of the following in the preamble to the rule?	F	F	M
• E. O. 12612, Federalism	F	F	M
• E.O. 12630, government Actions and Interference with Constitutionally Protected Property Rights	F	F	M
• E.O. 12866, Regulatory Planning and Review	F	F	M
• E.O. 12875, Enhancing the Intergovernmental Partnership	F	F	M
• E.O.12988, Civil Justice Reform	F	F	M
• E.O.13045, Protection of Children from Environmental Health Risks and Safety Risks	F	F	M
• Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify) <u>Small Business Regulatory Enforcement Fairness Act of 1996, Department of Health and Human Services guidelines.</u>			

ATTACHMENT H

OMB CLEARANCE PACKAGE

SUPPORTING STATEMENT FOR FINAL RULE
10 CFR PART 26, "FITNESS-FOR-DUTY PROGRAMS"

(OMB Clearance No. 3150-0146)

Revision Request

DESCRIPTION OF THE INFORMATION COLLECTION

The Office of Management and Budget (OMB) approved the information collections contained in the proposed rule on August 1, 1996. In response to public comments, we have modified the information collections in the final rule. Modifications to the supporting statement because of final rule changes are shown in redline and strikeout. A few additional modifications reflect changes not captured in the proposed rule.

These amendments to 10 CFR Part 26 modify the current fitness-for-duty (FFD) program requirements that apply to licensees authorized to operate nuclear power reactors and to licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material. The FFD program requirements will apply to 72 sites.

The rule is intended to ensure compatibility with changes made to the Department of Health and Human Services (HHS) testing guidelines, reduce unnecessary burdens, clarify requirements, and ensure continued protection of public health and safety.

F. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

10 CFR Part 26 sets forth requirements and standards for the establishment and maintenance of FFD programs that will provide reasonable assurance that licensee operations are conducted by reliable, trustworthy people who are not under the influence of any substance, legal or illegal, or who are not mentally or physically impaired from any cause that in any way interferes with their ability to safely and competently perform their duties. Fitness-for-duty programs developed in accordance with 10 CFR Part 26 are intended to create an environment that is free of drugs and the ill effects of such substances.

Changes in the information collection requirements from the current rule in 10 CFR Part 26 are identified below. Except as otherwise noted, these changes are intended to facilitate good management of the licensees' programs and ensure proper management of both the internal flow of information and the maintenance of program records. Several of the changes are one-time changes to policy, procedures, contracts, and so forth, and are intended to ensure good and consistent implementation of the requirements. We have discussed only those changes that affect the burden.

10 CFR 26.2(a) requires licensees to extend the coverage of their programs to certain FFD program personnel involved in the testing process, making an insignificant incremental burden for the maintenance of testing and training records.

The staff has withdrawn the proposed revision to 10 CFR 26.2(e) and the final version contains the current language. Upon reconsideration, the staff believes that the issue of FFD applicability to decommissioning plants should not be resolved in this rulemaking. Rather, the issue of FFD applicability should be resolved as part of a decommissioning regulatory improvement initiative under which the staff will reassess the technical and regulatory bases for applicability of the Commission's regulations in 10 CFR Part 50 for operating nuclear power plants.

10 CFR 26.2(f) allows persons performing Part 26 activities who are covered by a program regulated by another Federal agency or a State to be covered by only those elements of a licensee's FFD program that are not contained in the Federal agency or State program. As originally proposed, this revision would have required that the Federal agency or State program meet the "general performance objectives of the rule" to be acceptable as an alternative to the licensee's NRC-mandated FFD program. This subsection, as revised, now allows employees performing Part 26 activities to be covered by another Federal agency or State program as long the employees (1) are subject to pre-access (or pre-employment), random, and for-cause urine testing for the drugs specified in the HHS mandatory guidelines, and breath testing for alcohol, at or below NRC mandated cutoff levels; (2) have their urine specimens tested at a laboratory certified by HHS or the College of American Pathologists, or at another comparable certification laboratory; (3) take awareness training in specified subjects; and (4) have access to an impartial and objective procedure for appealing any findings of an FFD violation. Provisions must be in place for notifying the licensee(s) granting unescorted access about any FFD rule violated by the testing agency or organization.

10 CFR 26.20(a) and (d) requires licensees' written FFD policy to address offsite involvement with illegal drugs, subversion of the testing process, refusals to be tested, refusals to provide a specimen for analysis, and the use of prescription and over-the-counter medication. Licensees' plans and procedures require a one-time change.

10 CFR 26.20(d)(3) requires that written policies and procedures contain a description of immediate and subsequent actions that will be taken where persons are determined to have attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), by substituting specimens, or by any other means.

10 CFR 26.20(e)(1) requires a statement to be made by a person called in to be tested as to whether he or she considers himself or herself fit to perform the task assigned and whether he or she has consumed alcohol within the length of time stated in the pre-duty abstinence policy.

10 CFR 26.20(f) permits licensees to credit FFD program coverage (and access status) to certain workers being covered by another licensee.

10 CFR 26.21(b) decreases the frequency of FFD policy awareness refresher training from every 12 months to every 24 months, cutting the recordkeeping burden of such training in half.

10 CFR 26.22(c) provides flexibility by permitting a written exam in lieu of refresher training for two of three years. The development of a written exam is optional and there is no net change in the recordkeeping burden.

10 CFR 26.23(a)(2) requires licensees to modify contracts to ensure contractor and vendor personnel with a known history of substance abuse are revealed to the licensee.

10 CFR 26.24(a)(1) permits flexibility in pre-access testing and accepting recent test or program coverage in lieu of pre-access testing under specified conditions. The change is expected to reduce the number of pre-access tests and the associated recordkeeping burden.

10 CFR 26.24(a)(3)(ii) requires that for-cause drug and alcohol testing must be conducted as soon as practicable after the occurrence of an event. Except under documented unusual circumstances, such testing must be conducted within no more than 2 hours for an alcohol test and 8 hours for collection of a specimen for a drug test.

10 CFR 26.24(a)(5) adds a fifth category of testing, return-to-duty testing, to alleviate licensee burdens associated with random testing of persons who happen to be away from the site when selected. It also relieves some of the burdens associated with testing of persons returning to the site after extended absences. These clarifications of the Commission's intent are expected to reduce the number of random and pre-access tests and the associated recordkeeping burden.

10 CFR 26.24(f) requires that the medical review officer (MRO) shall complete the review of test results reported by the HHS-certified laboratory and notify licensee management as soon as practicable. Should the MRO's review not be completed within 14 days of the collection of a specimen, licensee management must be advised of available test results, the status of the review, the reasons for the delay, and appropriate recommendations.

10 CFR 26.24(h) requires a confirmatory blood alcohol concentration test showing a result between 0.02 percent and 0.04 percent be forwarded to the MRO for evaluation. A conforming change is at section 2.9(h) of Appendix A to Part 26.

10 CFR 26.27(a)(1) and (2) are revised to clarify the requirements for the written statement obtained from persons seeking unescorted access. The required history is limited to the past 5 years, and the individual must indicate his or her involvement with drugs, including treatment and whether he or she has ever been removed from Part 26 activities. The history must also describe the specific type, duration, and resolution of previous FFD program violations. Implementation requires a one-time modification to the drug history form.

Public comments received on 10 CFR 26.27(a)(4) indicated that valuable information is frequently obtained through checks of employment of 30 days or less. Therefore, by permitting licensees to ignore any period of 30 days or less that an applicant was not covered by an FFD program, the risk to public health and safety could be increased.

10 CFR 26.27(a)(6)(i) requires that if an individual has not previously been removed for violating a licensee's FFD policy, the licensee must either comply with the requirements

for full unescorted access or complete a suitable inquiry to verify the accuracy of the individual's written statement.

10 CFR 26.27(a)(7) requires that if an individual is returning to a licensee after an absence from the possibility of being tested under that site licensee's program for more than 60 days, the licensee must complete a suitable inquiry not later than 72 hours after unescorted access has been restored.

10 CFR 26.27(b) requires that personnel such as applicants who are impaired, those whose fitness may be questionable, and those determined to have violated the licensee's FFD policy, shall be immediately denied unescorted access or otherwise removed from activities. A return-to-duty test must be conducted before the individual may be returned to duty and, when applicable, a follow-up test should be administered. The licensee must retain a record of these tests.

10 CFR 26.27(c) requires that any act to subvert the testing process, including refusal to provide a specimen for testing, must be a violation of the licensee's FFD policy and must result in revocation of authorization to perform certain activities for a minimum of 3 years. A record of these actions must be retained until the license is terminated consistent with 10 CFR 26.71(c).

10 CFR 26.27(d) adds NRC contractors to the requirement that licensees report NRC personnel considered unfit for duty. This would have an insignificant impact because it would involve only a short telephone call reporting one event every 10 years.

10 CFR 26.28 expands the right to appeal an FFD policy violation determination to include applicants for unescorted access. It also codifies current practice by requiring that relevant records be corrected when an appeal is successful. This is anticipated to have a minimal impact.

10 CFR 26.29(c) incorporates requirements previously contained in Section 3.2 of Appendix A to Part 26 and clarifies that licensees, upon written request, must provide subject individuals with copies of all records pertaining to that individual's violations of a licensee's FFD policy. The change clarifies current requirements and is intended to ensure that all relevant records are promptly provided.

10 CFR 26.71(d) reduces the frequency of submitting program performance reports to once a year instead of every six months. Data on subversion attempts will now be collected and included in the annual report. The data are used by licensees and the NRC to monitor program performance and assess the need for change.

10 CFR 26.73(a)(2), (3), and (4) adds FFD program personnel as a third class of people whose negative acts would be reportable. It also requires reporting any act that would cast doubt on the integrity of the FFD program and reporting arrests of workers for distribution, possession, sale, or use of illegal drugs on or off site. The information is used by the NRC to determine if a problem exists that may require NRC response.

10 CFR 26.73(b) has not been modified by the rulemaking. It requires that notification must be made to the NRC Operations Center by telephone within 24 hours of the

discovery of a significant FFD event. In response to the burden estimate for the proposed rule (61 FR 20290), one commenter maintained that some burdens reported to the NRC are underestimated. He stated that each call to report a significant event may take only 15 minutes, but the preparation time required to compile and evaluate the necessary event information, inform management, and coordinate the call with licensing personnel may take at least an hour, and this time is not included in the estimate. Although the NRC did include some time for internal coordination, it believes that it did not include sufficient time for all the internal coordination and documentation described by the commenter. Therefore, the burden estimate for internal coordination has been increased from 15 minutes to 30 minutes.

10 CFR 26.80 reduces the frequency of licensee audits from every 12 months to at least once every 36 months, with the scope, depth, and frequency of interim audits to be based on performance. To make this determination, licensees will collect and review program performance data. Any burden reduction in developing audit reports would be offset by reports of interim audits stimulated by significant changes or problems and a continuing requirement to audit contracted services every 12 months.

Appendix A

2.1(b) allows licensees to test for any illegal drugs or any other substances suspected of having been abused and increases the number of records maintained.

2.2(a) requires that custody-and-control forms related to determinations of violations of the FFD policy must be retained as required by 10 CFR Part 26.71(b) and (c), or until the completion of all legal proceedings related to the violation, whichever is later. Custody-and-control forms recording specimens with negative test results and no FFD violations or anomalies may be destroyed after appropriate summary information has been recorded for program administration purposes.

2.4(d) requires custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service.

2.4(g)(4) eliminates the requirements for an individual to list prescription and over-the-counter medications he or she is ingesting.

2.4(g)(9) (plus old (15), old (24), and (j)) deletes requirements concerning the maintenance of a permanent record book. Appropriate notations of observations and other matters are made on the custody and control form and no longer need to be repeated in the permanent record book.

The staff has withdrawn the proposed revision to 10 CFR 2.4(g)(13) of Appendix A and the final version contains the current language regarding an acceptable temperature range. Upon reconsideration, the Commission has decided not to adopt a narrower temperature range. Insufficient data exists showing whether there would be a significant number of true positives identified using the more restricted temperature range that are currently classified as negatives. Thus, it is unclear whether the benefits of identifying

these true positives outweighs the cost of additional confirmatory testing for eliminating false positives.

2.7(d) requires the MRO to report any adulteration or dilution evidence to management immediately.

2.7(e) requires laboratories to determine specimen validity and detect evidence of adulteration or dilution. These findings will be included in the report of test results currently required by 2.7 (old g).

2.7(g)(5) requires an additional test for the *d* and *l* isomers of amphetamines. The results of this additional test will be included in the report of test results currently required by 2.7 (old g). Laboratory quality controls and inspection criteria must be provided for these specialized tests and will be described in the procedure manual currently required by 2.7(o)(1).

2.7(h)(1) requires that the HHS-certified laboratory report identify the substances tested for, whether positive or negative; the cut-off(s) for each; the specimen number assigned by the licensee; and the drug testing laboratory specimen identification number. The revised rule requires that any indications of tampering, adulteration, or dilution that may be present also be included in the report.

2.7(k) clarifies that the individual must be informed of his option to have the split specimen tested. In addition, a reminder has been added that the licensee must report all false positives as required in section 2.8(f). Burden is included in section 2.8(f).

2.7(n) requires that licensee contracts with laboratories must provide for the NRC and the licensees to obtain documents and data that may be needed to assure proper laboratory performance.

2.7(p)(1) requires a laboratory to retain its latest procedure manual as a record until at least 2 years after the laboratory is no longer under contract to an NRC licensee. This provision will ensure that the appropriate procedures are available should a testing result be challenged.

2.8(c)(iii)(2) requires that with each batch of specimens to be screened, a sufficient number of standards must be included to ensure and document the linearity of the assay method over time in the concentration area of the cut-off. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen must be documented.

2.8(d)(3) requires that the linearity and precision of the confirmatory testing method shall be periodically documented and that implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

2.8(f)(1) establishes a schedule for destroying records related to investigations into an unsatisfactory testing performance.

2.8(f)(2) adds a regular test specimen to those test specimens requiring prompt notification of the NRC by telephone should a false positive occur. This is expected to have a minimal impact because licensees are currently reporting such errors and only two have occurred since January 1990, and testing processes have improved.

2.9(g)(2) requires the MRO to report to licensees the medical determinations of fitness.

4.1(c) requires that contracts between licensees and the laboratories require implementation of all obligations of Appendix A applicable to the laboratories.

2. Agency Use of the Information

The NRC will use the required records and reports for one or more of the following purposes:

- to determine if there are problems requiring timely response by the NRC staff (NRC actions might vary depending on the circumstances, but would include immediate telephone contact with the licensee to discuss the event or followup at the site);
- to monitor compliance with 10 CFR Part 26; and
- to perform empirical evaluations of the evolving discipline in support of any future considerations, including analysis of trends and lessons learned.

3. Reduction of Burden Through Information Technology

Most licensees collect, store, and format fitness-for-duty data electronically; however, at the current time, no licensees submit information electronically. The NRC encourages the use of information technology for data collection and submittals.

The NRC has undertaken the task of initiating a rulemaking that will give licensees, applicants, and other entities the option to submit documents electronically to the NRC. The rulemaking, which will also provide the procedures for making electronic submittals, will facilitate the capture of documents into the Agency-wide Documents Access and Management System (ADAMS) which will become operational during FY2000. The NRC will continue to capitalize on information technology for improving information access, information distribution, and public interaction.

4. Effort To Identify Duplication and Use Similar Information

The collection of information required by this revision does not duplicate any other requirements for collection of information.

Current reporting requirements do not provide the necessary information on significant FFD events concerning FFD program personnel, subversion of the testing process, discovery of illegal drugs or alcohol in the protected area, and the arrest of a worker for the use, sale, or distribution of illegal drugs on or off site.

5. Effort To Reduce Small Business Burden

This information collection does not affect small businesses.

6. Consequences To the Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

Additional reports required by this rule will be limited to telephone reports on an as-needed basis and incremental data added to annual program performance reports. These reports are necessary to enable the licensee and the NRC to analyze and take appropriate actions. Without these reports, the NRC would be limited in its ability to take actions to correct program weaknesses.

7. Circumstances That Justify Variation From OMB Guidelines

FFD program violations will be reported by telephone within 24 hours and, therefore, are a variation from OMB guidelines. This requirement provides timely information with minimal burden on the licensees and is intended to provide further assurance that an event within the purview of the FFD rule will not have an adverse effect on public health and safety.

Retention of certain records in excess of 3 years has also been deemed necessary to ensure that the health and safety of the public will not be affected adversely by plant operations.

8. Consultations Outside the NRC

The requirements of 10 CFR Part 26 are discussed on a continuing basis with the Nuclear Energy Institute (NEI), the Substance Abuse and Mental Health Services Administration (SAMHSA), and licensees individually and at industry-wide meetings.

The public was given an opportunity to comment when the proposed rule was published in the Federal Register (61 FR 21146) on May 9, 1996. Response to comments received on the information collections is discussed in the preamble to the final rule. The burden for reporting FFD events was revised in response to a commenter's concerns.

9. Payments or Gifts to Respondents

Not applicable.

10. Confidentiality of the Information

Section 26.29(a) requires each licensee to collect personal information for the purpose of complying with 10 CFR Part 26 and to maintain a system of files and procedures for the protection of the personal information. The licensee will not report personal and sensitive information to the NRC. Changes to Section 26.29 permit disclosure of information to a contractor or vendor who legitimately seeks information for unescorted access decisions by licensees. It also allows disclosure of personal information collected in compliance with 10 CFR Part 26 to presiding officers of judicial or administrative proceedings initiated by the person who is the subject of the information.

11. Justification for Sensitive Questions

Section 26.29(a) requires each licensee to collect personal information for the purpose of complying with 10 CFR Part 26 and to maintain a system of files and procedures for the protection of the personal information.

In accordance with 10 CFR 26.73(a) and (b), and 26.71(d), the names of individuals need not be given in reports submitted to the NRC.

12. Estimate of Industry Burden and Costs

The costs and savings associated with information collection changes in the rule are given in Tables 1, 2, 3, and 4. Changes to the information collection requirements that merely clarify the requirements and do not increase or reduce burden are not included in the tables. These estimates are based, in part, on discussions with nuclear utility employees and on estimates made by NRC personnel who are familiar with the records and reports required by 10 CFR Part 26.

13. Estimates of Other Additional Costs

None.

14. Estimated Annual Cost to the Federal Government

The revised information collections proposed by in this rule would not significantly change the cost to the Federal Government.

This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Change in Burden or Cost

The final rule will reduce existing information collection requirements and will contain new information collections. The net effect would decrease the information collection burden by an estimated 9,400 hours. The major reductions are accomplished by reducing the submittal of program performance reports to once a year instead of every six months, deleting the requirement to maintain a permanent record book, reducing the investigative burden and associated records relating to suitable inquiries, and permitting prompt destruction of forms with negative test results. In FY 1993, an average of 3,308 negative test results were reported at each FFD program.

The principal reason for the burden change in the final rule is because the number of licensees was reduced from 74 to 72. Significant savings for licensees made by revisions in the final rule included Part 26.71(d) and Parts 2.2(a) and 2.4(g)(9) of Appendix A which halved the frequency of submitting program performance reports to NRC, deleted one recordkeeping requirement in its entirety, and reduced the record retention period for another.

16. Publication for Statistical Use

The NRC publishes an annual report that summarizes the results of the drug and alcohol testing programs. The report provides a description of licensees' fitness-for-duty programs.

17. Reason for Not Displaying the Expiration Date

The requirement will be contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

None.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this information collection.

Attachments:

1. Table 1 - Recordkeeping Requirements
2. Table 2 - Reporting Requirements
3. Table 3 - Recordkeeping/Savings
4. Table 4 - Reporting/Savings
5. Final Rule, 10 CFR Part 26

Table 1
Recordkeeping Requirements
10 CFR Part 26 Amendment
Fitness-For-Duty Programs

Subsection: Contents		No. of Sites	Burden Hours per Site	Total Burden Hours	Total Cost = Burden * \$141				
26.2(a): Coverage extended to FFD program personnel	2 (add 6) 37 (add 3)	0.6 0.3	1.2 <u>11.1</u> 12.3	\$1,734					
26.20(a) and (d): All one-time policy, procedure, and contract revisions (covering all of Part 26)	72	12	864	\$121,824					
26.20(d)(3): Description of actions to be taken for attempted subversion of testing	72	(included in 26.20 (a) and (d))	N/A	N/A					
26.20(e)(1): Statement from person to be tested called in	72	(included in 26.20 (a) and (d))	N/A	N/A					
26.22(c): Written exam in lieu of refresher training	72	0	0	0					

Table 1
Recordkeeping Requirements
10 CFR Part 26 Amendment
Fitness-For-Duty Programs

Subsection: Contents	No. of Sites	Burden Hours per Site	Total Burden Hours	Total Cost = Burden * \$141
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26.23(a)(2): Licensee contracts revised to cover persons with known history (one-time change included under 26.20)	72	(Included in 26.20)	N/A	N/A					
26.24(a)(3)(ii): Document circumstances for not testing within required period	72	0.10	7.2	\$1,015					
26.24(f): MRO review and report on test results received from HHS-certified lab	72	0.30	21.6	\$3,046					

26.24(h): MRO evaluations of low blood alcohol concentration	72	1	72	\$10,152					
26.27(a)(1) & (2): History of substance abuse*			72		20 persons * 0.1 hrs = 2 hrs		144		\$20,304
26.27(a)(1) & (2): History of substance abuse; one-time modification to drug history form			72 74		(Included in 26.20)		N/A		N/A
26.27(a)(2): Disclosure of specific type, duration, and resolution of previous FFD violations			72		1		72		\$10,152
26.27(a)(6)(i): Verify individual's written statement			72		1		72		\$10,152
26.27(a)(7): Suitable inquiry completed			72		(included in 26.27(a)(6)(i))		N/A		N/A
26.27(b): Record of return-to-duty and follow-up tests retained			72		1		72		\$10,152
26.28: Right to appeal extended to applicants and records corrected if appeal successful			72		3		216		\$30,456
26.29(c): Provide records of FFD violation			72		1		72		\$10,152
26.80: Collect data to determine audit frequency			72		1		72		\$10,152

Table 1
Recordkeeping Requirements
10 CFR Part 26 Amendment
Fitness-For-Duty Programs

Subsection: Contents	No. of Sites	Burden Hours per Site	Total Burden Hours	Total Cost = Burden * \$141
2.1(b) of Appendix A: Test for any abused drug or substance	72	1	72	\$10,152
2.4(d) of Appendix A: Tracking system for custody accountability of shipping containers	72	1	72	\$10,152
2.7(g)(5) of Appendix A: Records re: testing for d&l somers	72	Insignificant**	N/C	N/C
2.7(n) of Appendix A: Contract must permit obtaining info (one-time change included under 26.20, above)	72	(Included in 26.20)	N/A	N/A
2.7(p)(1) of Appendix A: Lab manual retention period established	72	N/A	N/A	N/A
2.8(c)(iii)(2) & (d)(3) of Appendix A: Document procedures to show carryover does not contaminate screening and confirmatory specimens (one-time annualized requirement)	72	1.10	79.2	\$11,167

Table 2
Reporting Requirements
10 CFR Part 26 Amendment
Fitness-For-Duty Programs

Subsection: Contents	No. of Sites	Reports per Site	Burden per Report	Total Burden Hours	Total Cost = Burden * \$141
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4.1(c) of Appendix A: Contracts to require labs to meet Appendix A	72	N/A (Included in 26.20)	N/A	N/A	N/A
TOTALS	-	-	1920.3	\$270,762	

*Licensees are currently obtaining statements concerning substance abuse history. The clarifications to the rule would require an estimated 20 persons per site per year to complete a declaration describing the type, duration, and resolution of any abuses during the past 5 years.

**The records would be included in the records of test results as currently required by 2.7(a) and 2.7(hr)(8) of Appendix A.

26.27(d): Add NRC contractors to report if unfit	72	Insignificant**	N/A	N/A	N/A
26.71(d): Data on subversion	72	1	1	72	\$10,152
26.73(a)(2), (3), & (4): Add reportable FFD events, FFD program personnel, arrests	72	2	0.5	72	\$10,152
26.73(b): Report FFD event within 24 hr	72	1	0.5	72	\$10,152
2.7(d) of Appendix A: MRO report to management	72	5	0.2	72	\$10,152

Table 2
Reporting Requirements
10 CFR Part 26 Amendment
Fitness-For-Duty Programs

Subsection: Contents	No. of Sites	Reports per Site	Burden per Report	Total Burden Hours	Total Cost = Burden * \$141
2.7(e) of Appendix A: Lab to include determination of specimen validity in report of test results	72	Approx. 3,000	Insignificant*	N/A	N/A
2.7(g)(5) of Appendix A: Special amphetamine tests to be included in report of test results	72	Approx. 300	Insignificant*	N/A	N/A
2.7(h)(1) of Appendix A HHS-certified report must include tampering, adulterating, or diluting	72	1	1	72	\$10,152
2.7(k) of Appendix A: Individual to be informed of option re: split specimen	72	40	Insignificant*	N/A	N/A
2.8(f)(2): Add regular specimen to false positives to be reported	72	Insignificant***	N/A	N/A	N/A
2.9(g)(2) of Appendix A: Medical determination of fitness	72	5	.2	72	\$10,152
TOTALS	-	-	-	432	\$60,912

*The results would be included in the report of test results as currently required by 2.7(g) of Appendix A.

**One short telephone report from the entire industry of an unfit NRC contractor could occur every 10 years.

***One telephone report from the entire industry of a false positive on a regular specimen could occur every 10 years.

Table 3
Recordkeeping/Savings
10 CFR Part 26 Amendment
Fitness-For-Duty Programs

Subsection: Contents	No. of Sites	Savings per Site	Total Hours Burden Reduction	Total = Savings * \$141
26.2(f): Eliminate duplicate testing	72	2	144	\$20,304
26.20(f): Credit access/FFD status	72 74	1	72	\$10,152
26.21(b): Decrease frequency of training	72	2 min/individual * 75 individual/site = 2.5	180	\$25,380
26.24(a)(1): Flexibility will reduce number of pre-access tests	72	2	144	\$20,304
26.24(a)(5): Return-to duty test and reporting by MRO	72	5	360	\$50,760
26.27(a)(4): Formerly 26.27(a)(3): Suitable Inquiries	72	0	0	0
26.27(c): Schedule for destroying records of subversion	72	Minimal	N/A	N/A
26.80: Reduce audit frequency and conduct interim audits	72	Net: no change	N/A	N/A
2.2(a) of Appendix A: Destroy chain-of-custody forms on negatives)	72	56	4,032	\$568,512

Table 3
Recordkeeping/Savings
10 CFR Part 26 Amendment
Fitness-For-Duty Programs

Subsection: Contents	No. of Sites	Savings per Site	Total Hours Burden Reduction	Total = Savings * \$141
2.4(g)(4) of Appendix A: Delete requirement to list medications	72	0.1 hr * 100 individual/site = 10hr/site	720	\$101,520
2.4(g)(9) [plus old (15), old (24), & (j)] of Appendix A: Delete requirement for permanent record book	72	0.02 hr/test * 2200 tests/site = 44 hrs/site	3,168	\$446,688
2.8(f)(1) of Appendix A: Schedule for destroying findings of testing process errors	72	1	72	\$10,152
TOTALS	-	-	8,892	\$1,253,772

Table 4
Reporting/Savings
10 CFR Part 26 Amendment
Fitness-For-Duty Programs

Subsection: Contents	No. of Sites	Savings per Site	Total Hours Burden Reduction	Total = Savings * \$141
26.71(d) (Reduce frequency of program performance reports to annual)	72	40	2,880	\$207,360
TOTALS	-	-	2,880	\$207,360

Table 4
Reporting/Savings
10 CFR Part 26 Amendment
Fitness-For-Duty Programs

Subsection: Contents	No. of Sites	Savings per Site	Total Hours Burden Reduction	Total
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