

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the Supporting Statement, and any additional documentation to: **Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.**

1. Agency/Subagency originating request <b>U.S. Nuclear Regulatory Commission</b>	2. OMB control number <input type="checkbox"/> a. <b>3150 - 0146</b> <input type="checkbox"/> b. None
3. Type of information collection (check one) <input type="checkbox"/> a. New collection <input checked="" type="checkbox"/> b. Revision of a currently approved collection <input type="checkbox"/> c. Extension of a currently approved collection <input type="checkbox"/> d. Reinstatement, <b>without change</b> , of a previously approved collection for which approval has expired <input type="checkbox"/> e. Reinstatement, <b>with change</b> , of a previously approved collection for which approval has expired <input type="checkbox"/> f. Existing collection in use without an OMB control number	4. Type of review requested (check one) <input checked="" type="checkbox"/> a. Regular <input type="checkbox"/> c. Delegated <input type="checkbox"/> b. Emergency - Approval requested by (date): 5. Will this information collection have a significant economic impact on a substantial number of small entities? <input type="checkbox"/> a. Yes <input checked="" type="checkbox"/> b. No
6. Requested expiration date <input type="checkbox"/> a. Three years from approval date <input checked="" type="checkbox"/> b. Other (Specify): <b>9/30/2002</b>	
7. Title <b>10 CFR Part 26, Fitness for Duty Programs</b>	
8. Agency form number(s) (if applicable) <b>Not applicable</b>	
9. Keywords <b>Drug abuse, Fitness for duty, Chemical testing</b>	
10. Abstract <b>Part 26 requires nuclear power plant licensees and licensees authorized to possess, use, or transport unirradiated Category I nuclear material to maintain fitness-for-duty programs to ensure that personnel are not under the influence of any substance or are mentally or physically impaired. The final rule implements provisions that reduce the burden for these information collection requirements.</b>	
11. Affected public (Mark primary with "P" and all others that apply with "X") <input type="checkbox"/> a. Individuals or households <input type="checkbox"/> d. Farms <input checked="" type="checkbox"/> b. Business or other for-profit <input type="checkbox"/> e. Federal Government <input type="checkbox"/> c. Not-for-profit institutions <input type="checkbox"/> f. State, Local or Tribal Government	12. Obligation to respond (Mark primary with "P" and all others that apply with "X") <input type="checkbox"/> a. Voluntary <input type="checkbox"/> b. Required to obtain or retain benefits <input checked="" type="checkbox"/> c. Mandatory
13. Annual reporting and recordkeeping hour burden a. Number of respondents <u>72</u> b. Total annual responses <u>44,144</u> 1. Percentage of these responses collected electronically <u>0.0</u> % c. Total annual hours requested <u>52,175</u> d. Current OMB inventory <u>61,575</u> e. Difference <u>(9,400)</u> f. Explanation of difference 1. Program change <u>(9,400)</u> 2. Adjustment _____	14. Annual reporting and recordkeeping cost burden (in thousands of dollars) a. Total annualized capital/startup costs <u>0</u> b. Total annual costs (O&M) <u>0</u> c. Total annualized cost requested <u>0</u> d. Current OMB inventory <u>0</u> e. Difference <u>0</u> f. Explanation of difference 1. Program change _____ 2. Adjustment _____
15. Purpose of information collection (Mark primary with "P" and all others that apply with "X") <input type="checkbox"/> a. Application for benefits <input type="checkbox"/> e. Program planning or management <input type="checkbox"/> b. Program evaluation <input type="checkbox"/> f. Research <input type="checkbox"/> c. General purpose statistics <input checked="" type="checkbox"/> g. Regulatory or compliance <input type="checkbox"/> d. Audit	16. Frequency of recordkeeping or reporting (check all that apply) <input checked="" type="checkbox"/> a. Recordkeeping <input checked="" type="checkbox"/> b. Third-party disclosure <input checked="" type="checkbox"/> c. Reporting <input checked="" type="checkbox"/> 1. On occasion <input type="checkbox"/> 2. Weekly <input type="checkbox"/> 3. Monthly <input type="checkbox"/> 4. Quarterly <input checked="" type="checkbox"/> 5. Semi-annually <input type="checkbox"/> 6. Annually <input type="checkbox"/> 7. Biennially <input type="checkbox"/> 8. Other (describe) _____
17. Statistical methods Does this information collection employ statistical methods? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	18. Agency contact (person who can best answer questions regarding the content of this submission) Name: <u>Garmon West</u> Phone: <u>301-415-1044</u>

D03

## 19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9.

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8 (b) (3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

- (a) It is necessary for the proper performance of agency functions;
- (b) It avoids unnecessary duplication;
- (c) It reduces burden on small entities;
- (d) It uses plain, coherent, and unambiguous terminology that is understandable to respondents;
- (e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;
- (f) It indicates the retention periods for recordkeeping requirements;
- (g) It informs respondents of the information called for under 5 CFR 1320.8 (b) (3):
  - (i) Why the information is being collected;
  - (ii) Use of information;
  - (iii) Burden estimate;
  - (iv) Nature of response (voluntary, required for a benefit, or mandatory);
  - (v) Nature of extent of confidentiality; and
  - (vi) Need to display currently valid OMB control number;
- (h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of the instructions);
- (i) It uses effective and efficient statistical survey methodology; and
- (j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Authorized Agency Official	Date
 Brenda Jo. Shelton, NRC Clearance Officer, Office of the Chief Information Officer	1/25/2001

SUPPORTING STATEMENT FOR FINAL RULE ~~PROPOSED 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 ~~7472~~ 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.*

A. 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.

~~10 CFR 26.2(e) would have allowed licensees at facilities in the process of being decommissioned to reduce the scope of the fitness-for-duty program to persons as deemed appropriate by the Commission. This would eliminate the need for licensees to submit, and the NRC to process, an exemption. 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) would allow persons covered by a program regulated by another Federal agency or State that meets the general performance objectives of Part 26 to not be subject to duplicate testing by a licensee. 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 as 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 be conducted as soon as practicable after the occurrence of an event. Except under documented unusual circumstances, such testing must be conducted within 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) 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.

~~10 CFR 26.27(a)(4) would have clarified that suitable inquiries need not be conducted for any period of 30 days or less that a person is not covered by an FFD program. The change reduces some of the investigative burden and associated records.~~ Based upon information obtained after publication of the proposed rule, the NRC has decided to withdraw this relaxation at **10 CFR 26.27(a)(4)**. 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.

**10 CFR 26.27(a)(6)(i)** requires, where temporary unescorted access is to be granted to an individual, that the individual must not have previously been removed for violating a licensee's FFD policy, and 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 of more than 60 days from the possibility of being tested under that licensee's program, 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, 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. 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). ~~would allow licensees to dispose of records five years following denial of any access authorization resulting from subversion.~~

**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)** would establish a destruction schedule so that licensees may dispose of chain-of-custody forms associated with FFD policy violations after 5 years and need not retain chain-of-custody forms recording no FFD violations or other anomalies after appropriate summary information has been recorded for program administration purposes.~~ 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 that 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.

~~**2.4(g)(13)** would have required that changes in acceptable temperature range and factors that were the basis for the range be reflected in licensee procedures. The burden for this one-time change is covered under 26.20. This specific change could be made with a pen and ink change to existing procedures. 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 exist 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 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 be periodically documented and that implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen 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 became 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 are reported by telephone within 24 hours and, therefore, are a variation from OMB guidelines. This requirement provides timely information 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 included as Attachment 5. 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 ~~proposed~~ 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 ~~12,000~~ 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 that 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. Response to Comments Received on  
Information Collections
6. 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 * \$141 423
26.2(a): Coverage extended to FFD program personnel	2 (add 6 )	0.6	1.2	\$1,734
	37 (add 3)	0.3	<u>11.1</u> 12.3	<del>\$1,513</del>
26.20(a) and (d): All one-time policy, procedure, and contract revisions (covering all of Part 26)	72 74	12	864 888	\$121,824 <del>\$109,224</del>
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
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

**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 * \$141 423
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 74	1	72 74	\$10,152 \$9,102
26.27(a)(1) & (2): History of substance abuse*	72 74	20 persons * 0.1 hrs = 2 hrs	144 148	\$20,304 \$10,204
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 74	1	72 74	\$10,152 \$9,102
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

**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 * \$141 423
26.28: Right to appeal extended to applicants and records corrected if appeal successful	72 74	3	216 222	\$30,456 \$27,306
26.29(c): Provide records of FFD violation	72 74	1	72 74	\$10,152 \$9,102
26.80: Collect data to determine audit frequency	72 74	1	72 74	\$10,152 \$9,102
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
2.4(g)(13) of Appendix A: Changes in temperature range and factors that were basis	72 74 —	0.10 0.05	7.2 3.7	\$1,015 \$455
2.7(g)(5) of Appendix A: Records re: testing for d&l somers	72 74	Insignificant**	N/C	N/C

**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 * \$141 423
2.7(n) of Appendix A: Contract must permit obtaining info (one-time change included under 26.20, above)	72 <del>74</del>	(Included in 26.20)	N/A	N/A
2.7(p)(1) of Appendix A: Lab manual retention period established	72 <del>74</del>	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
4.1(c) of Appendix A: Contracts to require labs to meet Appendix A	72 <del>74</del>	N/A (Included in 26.20)	N/A	N/A
<b>TOTALS</b>	-	-	1920.3 <del>1,534</del>	\$270,762 <del>\$188,682</del>

\*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.

**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 * \$141 423
<del>26.23(a)(2) Licensee contracts revised to cover persons with known history (one-time change included under 26.20)</del> (Moved to recordkeeping)	72 74	N/A (Included in 26.20)	N/A	N/A	N/A
26.27(d): Add NRC contractors to report if unfit	72 74	Insignificant**	N/A	N/A	N/A
26.71(d): Data on subversion	72	1	1	72	\$10,152 \$9,102
26.73(a)(2), (3), & (4): Add reportable FFD events, FFD program personnel, arrests	72 74	2	0.5	72	\$10,152 \$9,102
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 74	5	0.2	72 74	\$10,152 \$9,102
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

**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 * \$141 423
2.7(g)(5) of Appendix A: Special amphetamine tests to be included in report of test results	72 <del>74</del>	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 <del>74</del>	40	Insignificant*	N/A	N/A
2.8(f)(2): Add regular specimen to false positives to be reported	72 <del>74</del>	Insignificant***	N/A	N/A	N/A
2.9(g)(2) of Appendix A: Medical determination of fitness	72 <del>74</del>	5	.2	72 <del>74</del>	\$10,152 \$9,102
<b>TOTALS</b>	-	-	-	432 296	\$60,912 \$36,408

\*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 * \$141423
26.2(e) (Facilities being decommissioned)	Unknown**	Intermediate	N/A	N/A
26.2(f): Eliminate duplicate testing	72 74	2	144 148	\$20,304 \$10,204
26.20(f): Credit access/FFD status	72 74	1	72 74	\$10,152 \$9,102
26.21(b): Decrease frequency of training	72 74	2 min/individual * 75 individual/site = 2.5	180 185	\$25,380 \$22,755
26.24(a)(1): Flexibility will reduce number of pre-access tests	72 74	2	144 148	\$20,304 \$18,204
26.24(a)(5): Return-to duty test and reporting by MRO	72 74	5	360 370	\$50,760 \$45,510
26.27(a)(4): Formerly 26.27(a)(3): Suitable Inquiries	72 74	0 31.25	0 2,313	0 \$284,499
26.27(c): Schedule for destroying records of subversion	72 74	Minimal	N/A	N/A
26.80: Reduce audit frequency and conduct interim audits	72 74	Net: no change	N/A	N/A

**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 * \$141423
2.2(a) of Appendix A: Destroy chain-of-custody forms on negatives)	72 74	56	4,032	\$568,512 \$509,712
2.4(g)(4) of Appendix A: Delete requirement to list medications	72 74	0.1 hr * 100 individual/site = 10hr/site	720	\$101,520 \$91,020
2.4(g)(9) [plus old (15), old (24), & (j)] of Appendix A: Delete requirement for permanent record book	72 74	0.02 hr/test * 2200 tests/site = 44 hrs/site	3,168	\$446,688 \$400,488
2.4(g)(13) of Appendix A: New temperature range in collection procedures	72 74	N/A (Included in 26.20)	N/A	N/A
2.8(f)(1) of Appendix A: Schedule for destroying findings of testing process errors	72 74	1	72 74	\$10,152 \$9,102
TOTALS	-	-	8,892 41,452	\$1,253,772 \$1,408,596

**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 * \$141423
26.71(d) (Reduce frequency of program performance reports to annual)	72 74	40	2,880 2,960	\$207,360 \$364,080
TOTALS	-	-	2,880 2,960	\$207,360 \$364,080

RESPONSE TO COMMENTS RECEIVED ON  
INFORMATION COLLECTIONS CONTAINED IN PROPOSED RULE  
FOR 10 CFR PART 26

*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. 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.

*Other 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. NRC's response to requested clarifications of the information collections is discussed in the preamble to the rule.

*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.

**ATTACHMENT 2**  
**FEDERAL REGISTER NOTICE**

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

1. Type of submission, new, revision, or extension: Revision.
2. The title of the information collection: Final Rule, 10 CFR Part 26, "Changes to the Fitness for Duty Program"
3. The form number if applicable: Not applicable.
4. How often is the collection required: Annually and on occasion.

5. Who will be required or asked to report: All licensees authorized to construct or operate a nuclear power reactor and all licensees authorized to possess, use, or transport unirradiated Category 1 nuclear material.
6. An estimate of the number of responses: A reduction of 72 responses (semi-annual to annual report).
7. The estimated number of annual respondents: 72 licensees.
8. An estimate of the number of hours annually needed to complete the requirement or request: A reduction of approximately of 9,400 hours annually (131 hours per licensee) or a reduction of 2,450 reporting hours and 6,950 of recordkeeping hours.
9. An indication of whether Section 3504(h), Pub. L. 96-511 applies: Applicable.
10. Abstract: 10 CFR Part 26, "Fitness-For-Duty Programs," requires licensees to implement fitness-for-duty programs to assure that personnel are not under the influence of any substance or mentally or physically impaired, to retain certain records associated with the management of these programs, and to provide reports concerning the performance of the programs and certain significant events. Compliance with these requirements is mandatory for licensees subject to 10 CFR Part 26.

A revision to 10 CFR Part 26 modifies the information collection requirements to, among other less significant changes, (1) extend coverage to certain classes of fitness-for-duty programs; (2) require licensees to revise their written policy and procedure to incorporate minor administrative procedures, e.g., Medical Review Officer medical review procedures and changes to various technical guidelines contained in Appendix A of 10 CFR Part 26; (3) require all licensees to obtain information in addition to that currently provided in written form from individuals which would indicate whether the individual has a history of substance abuse; and (4) add fitness-for-duty personnel as a third class of people whose negative acts would be reported.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F23, Rockville, MD 20852. OMB clearance packages are available at the NRC worldwide web site <http://www.nrc.gov/NRC/PUBLIC/OMB/index.html>. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by (insert date 30 days after publication in the Federal Register).

Amy Farrell

Office of Information and Regulatory Affairs (3150-0146)

NEOB-10202

Office of Management and Budget

Washington, DC 20503

Comments can also be submitted by telephone at (202) 395-7318.

The NRC Clearance Officer is Brenda J. Shelton, 301-415-7233.

Dated at Rockville, Maryland, this      day of                      2001.

For the Nuclear Regulatory Commission.

---

Brenda J. Shelton, NRC Clearance Officer  
Office of the Chief Information Officer

Comments can also be submitted by telephone at (202) 395-7318.

The NRC Clearance Officer is Brenda J. Shelton, 301-415-7233.

Dated at Rockville, Maryland, this      day of                      2001.

For the Nuclear Regulatory Commission.

\_\_\_\_\_  
Brenda J. Shelton, NRC Clearance Officer  
Office of the Chief Information Officer

\*SEE PREVIOUS CONCURRENCE.

OFFICE	RSS:DIPM	E	RSS:DIPM	N	IOLB:DIPM	N				
NAME	GWest*		VOrdaz*		GTracy*					
DATE	01/ 19/01		01/19/01		01/19/01					
OFFICE	PIMB:PMAS		OGC		CIO					
NAME	DMcCain*		TRothchild*		BShelton					
DATE	01/22/01		01/24/01		01/ /01					

OFFICIAL RECORD COPY

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

1. Type of submission, new, revision, or extension: Revision.
2. The title of the information collection: Final Rule, 10 CFR Part 26, "Changes to the Fitness for Duty Program"
3. The form number if applicable: Not applicable.
4. How often is the collection required: Annually and on occasion.

5. Who will be required or asked to report: All licensees authorized to construct or operate a nuclear power reactor and all licensees authorized to possess, use, or transport unirradiated Category 1 nuclear material.
6. An estimate of the number of responses: A reduction of 72 responses (semi-annual to annual report).
7. The estimated number of annual respondents: 72 licensees.
8. An estimate of the number of hours annually needed to complete the requirement or request: A reduction of approximately of 9,400 hours annually (131 hours per licensee) or a reduction of 2,450 reporting hours and 6,950 of recordkeeping hours.
9. An indication of whether Section 3504(h), Pub. L. 96-511 applies: Applicable.
10. Abstract: 10 CFR Part 26, "Fitness-For-Duty Programs," requires licensees to implement fitness-for-duty programs to assure that personnel are not under the influence of any substance or mentally or physically impaired, to retain certain records associated with the management of these programs, and to provide reports concerning the performance of the programs and certain significant events. Compliance with these requirements is mandatory for licensees subject to 10 CFR Part 26.

A revision to 10 CFR Part 26 modifies the information collection requirements to, among other less significant changes, (1) extend coverage to certain classes of fitness-for-duty programs; (2) require licensees to revise their written policy and procedure to incorporate minor administrative procedures, e.g., Medical Review Officer medical review procedures and changes to various technical guidelines contained in Appendix A of 10 CFR Part 26; (3) require all licensees to obtain information in addition to that currently provided in written form from individuals which would indicate whether the individual has a history of substance abuse; and (4) add fitness-for-duty personnel as a third class of people whose negative acts would be reported.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F23, Rockville, MD 20852. OMB clearance packages are available at the NRC worldwide web site <http://www.nrc.gov/NRC/PUBLIC/OMB/index.html>. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by (insert date 30 days after publication in the Federal Register).

Amy Farrell

Office of Information and Regulatory Affairs (3150-0146)

NEOB-10202

Office of Management and Budget

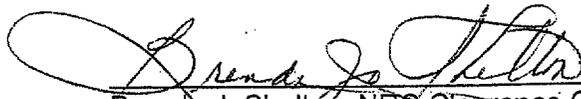
Washington, DC 20503

Comments can also be submitted by telephone at (202) 395-7318.

The NRC Clearance Officer is Brenda J. Shelton, 301-415-7233.

Dated at Rockville, Maryland, this 25<sup>th</sup> day of January 2001.

For the Nuclear Regulatory Commission.

  
Brenda J. Shelton, NRC Clearance Officer  
Office of the Chief Information Officer

**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](mailto:fitnessforduty@nrc.gov) or Richard P. Rosano of the same address, telephone: (301) 415-2933, e-mail: [fitnessforduty@nrc.gov](mailto: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 spectropscopy) 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 inject, 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 phesylproporolamine. 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 change<sup>1</sup> for its backfitting

---

<sup>1</sup>By "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 backfit<sup>2</sup> as well as the substantive requirement for performing the backfit analysis under paragraph (a)(3)<sup>3</sup> 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 stability<sup>4</sup>. 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.

<sup>2</sup>10 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)

<sup>3</sup>10 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)

<sup>4</sup>By 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 comment<sup>5</sup>, 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:

---

<sup>5</sup>The 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.<sup>6</sup>

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

---

<sup>6</sup>The 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.<sup>7</sup> 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.

---

<sup>7</sup>When 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.<sup>8</sup>

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 26<sup>9</sup>. Therefore, to the extent that the FFD Rule's

---

<sup>8</sup>The 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.

<sup>9</sup>The 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.
- 26.23 Contractors and vendors.
- 26.24 Chemical and alcohol testing.
- 26.25 Employee assistance programs (EAP).
- 26.27 Management actions and sanctions to be imposed.
- 26.28 Appeals.
- 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.
- 2.9 Reporting and Review of Results.

*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 <sup>1</sup>	300
Phencyclidine	25
Amphetamines	1,000
Alcohol <sup>2</sup>	0.04% BAC

<sup>1</sup>25 ng/ml is immunoassay specific for free morphine.

<sup>2</sup>Percent, 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 <sup>1</sup>	15
Cocaine metabolite <sup>2</sup>	150
Opiates:	
Morphine	300
Codeine	300
6-Acetylmorphine <sup>3</sup>	10
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine <sup>4</sup>	500
Alcohol <sup>5</sup>	0.04% BAC

<sup>1</sup>Delta-9-tetrahydrocannabinol-9-carboxylic acid.

<sup>2</sup>Benzoylcegonine.

<sup>3</sup>Test for 6-AM when the confirmatory test shows a morphine concentration exceeding 2,000 ng/ml.

<sup>4</sup>Specimen must also contain amphetamine at a concentration  $\geq$  200 ng/ml.

<sup>5</sup>Percent, 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.