

July 13, 2000

MEMORANDUM TO: Brenda J. Shelton, Chief  
Records Management Branch  
Division of Information Management  
Office of the Chief Information Officer

FROM: Glenn M. Tracy, Chief ***/RA/***  
Operator Licensing, Human Performance  
and Plant Support Branch  
Division of Inspection Program Management  
Office of Nuclear Reactor Regulation

SUBJECT: SUPPORTING STATEMENT AND FEDERAL REGISTER NOTICE FOR  
THE FINAL FITNESS-FOR-DUTY RULE (10 CFR PART 26)

By staff requirements memorandum (SRM) dated July 5, 2000, the Commission directed the staff to modify the fitness-for-duty (FFD) rulemaking package as follows: 1) remove the requirement imposing a more restrictive temperature range for an acceptable urine specimen (Sections 2.4(g)(13) and (15) of Appendix A) and 2) remove the requirement that a medical determination of fitness be performed to evaluate all employees tested for cause, including those who test negative. In addition, the SRM indicated that the staff should make conforming revisions to the rulemaking package and submit the revised rulemaking package to the Commission by July 23, 2000.

The revised supporting statement (Attachment 1) and Federal Register notice (Attachment 2) for the OMB clearance and a redline and strikeout of the revised FFD rule (Attachment 3) are attached. If you have any questions regarding these documents, please contact Garmon West at 415-1044.

Attachments: As Stated

July 13, 2000

MEMORANDUM TO: Brenda J. Shelton, Chief  
Records Management Branch  
Division of Information Management  
Office of the Chief Information Officer

FROM: Glenn M. Tracy, Chief  
Operator Licensing, Human Performance  
and Plant Support Branch  
Division of Inspection Program Management  
Office of Nuclear Reactor Regulation

SUBJECT: SUPPORTING STATEMENT AND FEDERAL REGISTER NOTICE FOR  
THE FINAL FITNESS-FOR-DUTY RULE (10 CFR PART 26)

By staff requirements memorandum (SRM) dated July 5, 2000, the Commission directed the staff to modify the fitness-for-duty (FFD) rulemaking package as follows: 1) remove the requirement imposing a more restrictive temperature range for an acceptable urine specimen (Sections 2.4(g)(13) and (15) of Appendix A) and 2) remove the requirement that a medical determination of fitness be performed to evaluate all employees tested for cause, including those who test negative. In addition, the SRM indicated that the staff should make conforming revisions to the rulemaking package and submit the revised rulemaking package to the Commission by July 23, 2000.

The revised supporting statement (Attachment 1) and Federal Register notice (Attachment 2) for the OMB clearance and a redline and strikeout of the revised FFD rule (Attachment 3) are attached. If you have any questions regarding these documents, please contact Garmon West at 415-1044.

Attachments: As Stated

DISTRIBUTION

CCarpenter                      MMalloy                      SFrattali                      BStMary                      DMcCain  
DOCUMENT NAME: G:\OLB\RSS\WEST\Final Fitness For Duty Rule\Rev3 to RS Version of Supporting Statement and FRN to Brenda Shelton.wpd

"C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

\*SEE PREVIOUS CONCURRENCE.

OFFICE	RSS:DIPM	E	RSS:DIPM	N	IOLB:DIPM	
NAME	GWest*		RPRosano*		GTracy*	
DATE	7/12/00		7/13/00		7/13/00	

OFFICIAL RECORD COPY

**ATTACHMENT 1**  
**SUPPORTING STATEMENT**

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 ~~74~~<sup>72</sup> 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 allow 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 clarify 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.~~ **Public comments received on 10 CFR 26.27(a)(4) indicated that valuable information is frequently obtained through checks of employment of 30 days or less. Therefore, by permitting licensees to ignore any period of 30 days or less that an applicant was not covered by an FFD program, the risk to public health and safety could be increased.**

**10 CFR 26.27(a)(6)(i)** requires that if an individual has not previously been removed for violating a licensee's FFD policy, the licensee must either comply with the requirements for full unescorted access or complete a suitable inquiry to verify the accuracy of the individual's written statement.

**10 CFR 26.27(a)(7)** requires that if an individual is returning to a licensee after an absence 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) requires that changes in acceptable temperature range and factors that were the basis for the range must 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 exists showing whether there would be a significant number of true positives identified using the more restricted temperature range that are currently classified as negatives. Thus, it is unclear whether the benefits of identifying these true positives outweighs the cost of additional confirmatory testing for eliminating false positives.**

**2.7(d)** requires the MRO to report any adulteration or dilution evidence to management immediately.

**2.7(e)** requires laboratories to determine specimen validity and detect evidence of adulteration or dilution. These findings will be included in the report of test results currently required by 2.7 (old g).

**2.7(g)(5)** requires an additional test for the *d* and *l* isomers of amphetamines. The results of this additional test will be included in the report of test results currently required by 2.7 (old g). Laboratory quality controls and inspection criteria must be provided for these specialized tests and will be described in the procedure manual currently required by 2.7(o)(1).

**2.7(h)(1)** requires that the HHS-certified laboratory report identify the substances tested for, whether positive or negative; the cut-off(s) for each; the specimen number assigned by the licensee; and the drug testing laboratory specimen identification number. The revised rule requires that any indications of tampering, adulteration, or dilution that may be present also be included in the report.

**2.7(k)** clarifies that the individual must be informed of his option to have the split specimen tested. In addition, a reminder has been added that the licensee must report all false positives as required in section 2.8(f). Burden is included in section 2.8(f).

**2.7(n)** requires that licensee contracts with laboratories must provide for the NRC and the licensees to obtain documents and data that may be needed to assure proper laboratory performance.

**2.7(p)(1)** requires a laboratory to retain its latest procedure manual as a record until at least 2 years after the laboratory is no longer under contract to an NRC licensee. This provision will ensure that the appropriate procedures are available should a testing result be challenged.

**2.8(c)(iii)(2)** requires that, with each batch of specimens to be screened, a sufficient number of standards 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 will be reported by telephone within 24 hours and, therefore, are a variation from OMB guidelines. This requirement provides timely information with minimal burden on the licensees and is intended to provide further assurance that an event within the purview of the FFD rule will not have an adverse effect on public health and safety.

Retention of certain records in excess of 3 years has also been deemed necessary to ensure that the health and safety of the public will not be affected adversely by plant operations.

8. Consultations Outside the NRC

The requirements of 10 CFR Part 26 are discussed on a continuing basis with the Nuclear Energy Institute (NEI), the Substance Abuse and Mental Health Services Administration (SAMHSA), and licensees individually and at industry-wide meetings.

The public was given an opportunity to comment when the proposed rule was published in the Federal Register (61 FR 21146) on May 9, 1996. Response to comments received on the information collections is **attached**. ~~discussed in the preamble to the final rule.~~ The burden for reporting FFD events was revised in response to a commenter's concerns.

9. Payments or Gifts to Respondents

Not applicable.

10. Confidentiality of the Information

Section 26.29(a) requires each licensee to collect personal information for the purpose of complying with 10 CFR Part 26 and to maintain a system of files and procedures for the protection of the personal information. The licensee will not

report personal and sensitive information to the NRC. Changes to Section 26.29 permit disclosure of information to a contractor or vendor who legitimately seeks information for unescorted access decisions by licensees. It also allows disclosure of personal information collected in compliance with 10 CFR Part 26 to presiding officers of judicial or administrative proceedings initiated by the person who is the subject of the information.

11. Justification for Sensitive Questions

Section 26.29(a) requires each licensee to collect personal information for the purpose of complying with 10 CFR Part 26 and to maintain a system of files and procedures for the protection of the personal information.

In accordance with 10 CFR 26.73(a) and (b), and 26.71(d), the names of individuals need not be given in reports submitted to the NRC.

12. Estimate of Industry Burden and Costs

The costs and savings associated with information collection changes in the rule are given in Tables 1, 2, 3, and 4. Changes to the information collection requirements that merely clarify the requirements and do not increase or reduce burden are not included in the tables. These estimates are based, in part, on discussions with nuclear utility employees and on estimates made by NRC personnel who are familiar with the records and reports required by 10 CFR Part 26.

13. Estimates of Other Additional Costs

None.

14. Estimated Annual Cost to the Federal Government

The revised information collections proposed by in this rule would not significantly change the cost to the Federal Government.

This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Change in Burden or Cost

The ~~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 because the number of licensees was reduced from 74 to 72. Significant savings for licensees made by revisions in the final rule included Part 26.71(d) and Parts 2.2(a) and 2.4(g)(9) of Appendix A which halved the frequency of submitting program performance reports to NRC, deleted one recordkeeping requirement in its entirety, and reduced the record retention period for another.

16. Publication for Statistical Use

The NRC publishes an annual report that summarizes the results of the drug and alcohol testing programs. The report provides a description of licensees' fitness-for-duty programs.

17. Reason for Not Displaying the Expiration Date

The requirement will be contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

None.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this information collection.

Attachments:

1. Table 1 - Recordkeeping Requirements
2. Table 2 - Reporting Requirements
3. Table 3 - Recordkeeping/Savings
4. Table 4 - Reporting/Savings
5. ~~Proposed~~ Final Rule, 10 CFR Part 26
6. Response to Comments Received on Information Collections

**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 <del>423</del>
26.2(a): Coverage extended to FFD program personnel	2 (add 6 ) 37 (add 3)	0.6 0.3	1.2 <u>11.1</u> 12.3	\$1,734 <del>\$1,513</del>
26.20(a) and (d): All one-time policy, procedure, and contract revisions (covering all of Part 26)	72 <del>74</del>	12	864 <del>888</del>	\$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 <del>423</del>
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 <del>74</del>	1	72 <del>74</del>	\$10,152 <del>\$9,102</del>
26.27(a)(1) & (2): History of substance abuse*	72 <del>74</del>	20 persons * 0.1 hrs = 2 hrs	144 <del>148</del>	\$20,304 <del>\$10,204</del>
26.27(a)(1) & (2): History of substance abuse; one-time modification to drug history form	72 <del>74</del>	(Included in 26.20)	N/A	N/A
26.27(a)(2): Disclosure of specific type, duration, and resolution of previous FFD violations	72 <del>74</del>	1	72 <del>74</del>	\$10,152 <del>\$9,102</del>
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 <del>74</del>	3	216 <del>222</del>	\$30,456 \$27,306
26.29(c): Provide records of FFD violation	72 <del>74</del>	1	72 <del>74</del>	\$10,152 \$9,102
26.80: Collect data to determine audit frequency	72 <del>74</del>	1	72 <del>74</del>	\$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 <del>74</del> -	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 <del>74</del>	Insignificant**	N/C	N/C
2.7(n) of Appendix A: Contract must permit obtaining info (one-time change included under 26.20, above)	72 <del>74</del>	(Included in 26.20)	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 * \$141 123
2.7(p)(1) of Appendix A: Lab manual retention period established	72 <del>74</del>	N/A	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 \$188,682	

\*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 <del>123</del>
<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)	<del>74</del> 72	N/A (Included in 26.20)	N/A	N/A	N/A
26.27(d): Add NRC contractors to report if unfit	<del>74</del> 72	Insignificant**	N/A	N/A	N/A
26.71(d): Data on subversion	<del>74</del> 72	1	1	72	\$10,152 <del>\$9,102</del>
26.73(a)(2), (3), & (4): Add reportable FFD events, FFD program personnel, arrests	<del>74</del> 72	2	0.5	72	\$10,152 <del>\$9,102</del>
26.73(b): Report FFD event within 24 hr	<del>74</del> 72	1	0.5	72	\$10,152
2.7(d) of Appendix A: MRO report to management	<del>74</del> 72	5	0.2	72 <del>74</del>	\$10,152 <del>\$9,102</del>
2.7(e) of Appendix A: Lab to include determination of specimen validity in report of test results	<del>74</del> 72	Approx. 3,000	Insignificant*	N/A	N/A
2.7(g)(5) of Appendix A: Special amphetamine tests to be included in report of test results	<del>74</del> 72	Approx. 300	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
					123
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 74	40	Insignificant*	N/A	N/A
2.8(f)(2): Add regular specimen to false positives to be reported	72 74	Insignificant***	N/A	N/A	N/A
2.9(g)(2) of Appendix A: Medical determination of fitness	72 74	5	.2	72 74	\$10,152 \$9,102
TOTALS	-	-	-	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 * <del>\$141</del> 123
26.2(e) (Facilities being decommissioned)	Unknown**	Intermediate	N/A	N/A
26.2(f): Eliminate duplicate testing	<del>72</del> 74	2	<del>144</del> 148	<del>\$20,304</del> \$10,204
26.20(f): Credit access/FFD status	<del>72</del> 74	1	<del>72</del> 74	<del>\$10,152</del> \$9,102
26.21(b): Decrease frequency of training	<del>72</del> 74	2 min/individual * 75 individual/site = 2.5	<del>180</del> 185	<del>\$25,380</del> \$22,755
26.24(a)(1): Flexibility will reduce number of pre-access tests	<del>72</del> 74	2	<del>144</del> 148	<del>\$20,304</del> \$18,204
26.24(a)(5): Return-to duty test and reporting by MRO	<del>72</del> 74	5	<del>360</del> 370	<del>\$50,760</del> \$45,510
26.27(a)(4): Formerly 26.27(a)(3): Suitable Inquiries	<del>72</del> 74	<del>0</del> 31.25	<del>0</del> 2,313	<del>0</del> \$284,499
26.27(c): Schedule for destroying records of subversion	<del>72</del> 74	Minimal	N/A	N/A
26.80: Reduce audit frequency and conduct interim audits	<del>72</del> 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 * <del>\$141,423</del>
2.2(a) of Appendix A: Destroy chain-of-custody forms on negatives)	<del>72</del> 74	56	4,032	<del>\$568,512</del> \$509,712
2.4(g)(4) of Appendix A: Delete requirement to list medications	<del>72</del> 74	0.1 hr * 100 individual/site = 10hr/site	720	<del>\$101,520</del> \$91,020
2.4(g)(9) [plus old (15), old (24), & (j)] of Appendix A: Delete requirement for permanent record book	<del>72</del> 74	0.02 hr/test * 2200 tests/site = 44 hrs/site	3,168	<del>\$446,688</del> \$400,488
2.4(g)(13) of Appendix A: New temperature range in collection procedures	<del>72</del> 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	<del>72</del> 74	1	<del>72</del> 74	<del>\$10,152</del> \$9,102
TOTALS	-	-	<del>8,892</del> 11,452	<del>\$1,253,772</del> \$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 * <del>\$141,423</del>
26.71(d) (Reduce frequency of program performance reports to annual)	72 <del>74</del>	40	2,880 <del>2,960</del>	\$207,360 <del>\$364,080</del>
TOTALS	-	-	2,880 <del>2,960</del>	\$207,360 <del>\$364,080</del>

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, 2120 L Street, NW (lower level), Washington, DC. 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).

Erik Godwin

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) 395-3087.

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

Dated at Rockville, Maryland, this      day of                      2000.

For the Nuclear Regulatory Commission.

---

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

**ATTACHMENT 3**

**TEXT OF RULE**

## PART 26--FITNESS FOR DUTY PROGRAMS

### GENERAL PROVISIONS

- 26.1 Purpose.
- 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.

*SSNM* means Strategic Special Nuclear Material.

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

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

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

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

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

#### **§ 26.4 Interpretations.**

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

#### **§ 26.6 Exemptions.**

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

#### **§ 26.7 Communications**

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part must be addressed to the NRC Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Copies of all communications must be sent to the appropriate regional office and resident inspector. Communications and reports may be delivered in person at the Commission's offices L S at

11555 Rockville Pike, One White Flint North, Rockville, Maryland, or at the Commission's Public Document Room located at 2120 L Street, NW (Lower Level), Washington, DC.

### **§ 26.8 Information collection requirements: OMB approval.**

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

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

## GENERAL PERFORMANCE OBJECTIVES

### **§ 26.10 General performance objectives.**

Fitness-for-duty programs must:

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

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

## PROGRAM ELEMENTS AND PROCEDURES

### **§ 26.20 Written policy and procedures.**

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

(a) An overall description of licensee policy on fitness for duty. The policy must address use of and offsite involvement with illegal drugs, abuse of legal drugs, subversion of the testing process, and refusals to provide a specimen for testing. A clear and concise written statement of this policy must be prepared and be in sufficient detail to provide affected individuals with information on what is expected of them, and what consequences may result from lack of adherence to the policy. This statement must be readily available to all persons subject to the policy.

(1) As a minimum, the written policy must prohibit the consumption of alcohol--

(i) Within an abstinence period of at least 5 hours preceding any scheduled working tour, and

(ii) During the period of any working tour.

(2) Licensee policy should also address other factors that could affect fitness for duty such as mental stress, fatigue, illness, and the use of prescription and over-the-counter medications that could cause impairment.

(b) A description of programs which are available to personnel desiring assistance in dealing with drug, alcohol, or other problems that could adversely affect the performance of activities within the scope of this part.

(c) Procedures to be used in testing for drugs and alcohol, including procedures for protecting individuals providing a specimen and the integrity of the specimen, and the quality controls used to ensure the test results are valid and attributable to the correct individual.

(d) A description of immediate and follow-on actions which will be taken, and the procedures to be used, in those cases where persons who are employed by licensees, vendors, or contractors, and are assigned to duties within the scope of this part, are determined to have--

(1) Been involved in the use, sale, or possession of illegal drugs;

(2) Consumed alcohol during the mandatory pre-work abstinence period, while on duty, or to excess before reporting to duty as demonstrated with a test that can be used to determine blood alcohol concentration;

(3) Attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means; or

(4) Refused to provide a specimen for analysis.

(e) A procedure that will ensure that persons called in to perform an unscheduled working tour are fit to perform the task assigned. As a minimum, this procedure must--

(1) Require a statement to be made by a called-in person as to whether he or she considers himself or herself fit to perform the task assigned and whether he or she has consumed alcohol within the length of time stated in the pre-duty abstinence policy;

(2) If alcohol has been consumed within this period and the person is called in, require a determination of fitness for duty by breath analysis or other means (collection of urine under § 26.24(a)(3) is not required); and

(3) Require the establishment of controls and conditions under which a person who has been called-in can perform work, if necessary, although alcohol has been consumed. Consumption of alcohol during the abstinence period shall not by itself preclude a licensee from using individuals needed to respond to an emergency.

(f) Licensees seeking to grant unescorted access pursuant to 10 CFR 73.56 to personnel covered by another licensee's FFD program that complies with this part may credit that licensee's program through verification that the individual is currently and will continue to be subject to the random testing and behavioral observation programs of either his or her employer or those of the host licensee.

## **§ 26.21 Policy communications and awareness training.**

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

(1) Licensee policy and procedures, including the methods that will be used to implement the policy;

(2) The personal and public health and safety hazards associated with the use of illegal drugs and the abuse of legal drugs including alcohol;

(3) The effect of prescription and over-the-counter drugs and dietary conditions on job performance and on chemical test results, and the role of the MRO;

(4) Employee assistance programs provided by the licensee; and

(5) What is expected of them and what consequences may result from lack of adherence to the policy,

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

#### **§ 26.22 Training of supervisors and escorts.**

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

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

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

(c) Initial training for escorts and supervisors employed by licensees must be completed before assignment of duties within the scope of this part, except that for an employee's first assignment to supervisory duties within the scope of this part, the initial training must be completed as soon as feasible but no later than 3 months following this assignment. Initial training for supervisors employed by contractors must be completed before their assignment to duties within the scope of this part or within 10 days after the first assignment to on-site supervisory duties within the scope of this part. Refresher training must be completed on a nominal 12-month frequency, or more frequently where the need is indicated. A written examination on the training material given on a nominal 12-month frequency may be used in lieu of refresher training for escorts and supervisors employed by licensees. The written examination must require a demonstration of adequate knowledge of the areas covered in paragraph (a) of this section. Refresher training for escorts and supervisors employed by licensees must be completed on a nominal 36-month frequency even if examinations are used to fulfill this requirement during the interim period. A record of the training or examination in lieu of training must be retained for a period of at least 3 years. Licensees may accept training of individuals who have been subject to a part 26 program and who have had initial or refresher training within the 12 months before assignment, provided that training by the accepting licensee in the topics covered by paragraphs (a) (1), (2), and (5) of this section is completed before assignment to duties within the scope of this part.

### **§ 26.23 Contractors and vendors.**

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

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

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

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

### **§ 26.24 Chemical and alcohol testing.**

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

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

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

(B) Has no history of substance abuse.

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

(2) Random drug and alcohol testing must be unannounced and imposed in a statistically random and unpredictable manner so that all persons in the population subject to testing have an approximately equal probability of being selected and tested. Random testing must include testing during all types of work periods, including weekends, backshifts, and holidays. The tests must be administered so that a person completing a test is immediately eligible for another unannounced test. At a minimum, random tests must be administered on a nominal weekly frequency and at various times during the day. Reasonable efforts must be made to test persons selected for random testing. Persons off site when selected for testing, and not reasonably available for testing in a timely manner, must be tested at the earliest reasonable and practical opportunity and without notification to the individual until immediately prior to his or her reporting for the test. Such tests will also fulfill any return-to-duty testing

required for such persons, and must be reported to the NRC as random tests. Random testing must be conducted at an annual rate equal to at least 50 percent of the workforce.

(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** ~~medical~~ determination of fitness, may be returned to duty pending results of urinalysis for drugs. For-cause drug and alcohol testing must be conducted as soon as practicable after the occurrence of the event. Except under documented unusual circumstances, such testing must be conducted within no more than 2 hours for an alcohol test and 8 hours for specimen collection for a drug test.

(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 licensee shall establish the temperature range within which the specimen temperature must fall based on site specific factors that influence the results, to include the type of temperature measuring devices used, the ambient temperature, time from urination to completion of the temperature measurement, and other factors. The licensee shall clearly specify the temperature range and the factors that were the basis for the range in its collection procedures.~~

~~The temperature range of an acceptable urine specimen must be within a band of 3°C/6°F or less, with a lower limit not lower than 34°C/94°F. The time from urination to temperature measurement must in no case exceed 4 minutes, 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 ~~and not less than 34°C/94°F.~~

(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>Benzoyllecgonine.

<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** include, but is not limited to, 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) In the evaluation of all for-cause test results;~~

~~(iii) 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;~~

~~(iv) 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~~

~~(v) 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.

Date at Rockville, Maryland, this \_\_\_\_\_ day of \_\_\_\_\_, 1999.

For the Nuclear Regulatory Commission.

---

Annette Vietti-Cook,  
Secretary of the Commission