Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 26

RIN 3150–AF12

Modifications to Fitness-For-Duty Program Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) proposes to amend its regulations to modify the current Fitness-For-Duty Program (FFD) requirements. The proposed amendments would apply to all licensees authorized to construct or operate a nuclear power reactor and all licensees authorized to possess or transport Category I nuclear material. The proposed rule is intended to ensure compatibility with changes made to the Department of Health and Human (HHS) testing guidelines, reduce unnecessary burdens, and ensure continued protection of public health and safety.

The NRC specifically requests comments on a number of issues and, in particular, as to whether the changes would provide a substantial increase in the overall protection of the public health and safety and the common defense and security, whether the rule as whole does not constitute a backfit since the rule's cumulative effect is to ease licensee burdens or leave them essentially the same, whether those subject to the rule would not object to the new requirements in view of their perception of overall benefit and, if so, whether their non-objection could be grounds for not applying the backfit rule.

DATES: The comment period expires August 7, 1996. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Mail comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Docketing and Service Branch.

Deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, Maryland between 7:30 am and 4:15 pm on Federal workdays.

Copies of the draft regulatory analysis, comments received, the Americans With Disabilities Act Technical Assistance Manual, HHS's Medical Review Officer Manual, and NIDA's Technical Advisory of March 11, 1991, may be examined at: the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

Copies of NUREG/CR–5784, ''Fitness for Duty in the Nuclear Power Industry: A Review of the First Year of Program Performance and an Update of the Technical Issues,'' NUREG–1385, ''Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions,'' and NUREG/CR–5758, ''Fitness for Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports,'' CY 1994, Volume 5, may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402–9328. Copies are also available from the National Technical Information Service, 5282 Port Royal Road, Springfield, VA 22161. A copy is available for inspection and/or copying in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Loren L. Bush, Jr., Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 415–2944.

SUPPLEMENTARY INFORMATION:

Background

The NRC is proposing to amend its regulations on ''Fitness-for-Duty Programs,'' as part of its ongoing activities to improve its regulations.

The objective of the licensee's fitness-for-duty program is to provide reasonable assurance that nuclear power plant personnel are reliable, trustworthy, and 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. Fitness-for-duty programs developed under the requirements of 10 CFR Part 26 are intended to create an environment which is free of drugs and the effects of such substances.

In its deliberation of the many issues associated with the rulemaking, the Commission desired that the rule ensure a proper balance between safeguarding individual rights and the Commission's responsibility to protect public health and safety. The changes proposed in this rulemaking are intended to be consistent with the Commission's original goals and to ensure there is a proper balance between the Commission's responsibility for protecting the public health and safety and its interest in protecting individual employee rights from unconstitutional invasion of their right to privacy.

The NRC has reviewed the experience gained since publication of the rule on June 7, 1989 (54 FR 24468), which was implemented by licensees January 3, 1990. NRC review included information from several sources, such as inspections, periodic reports by licensees on program performance, reports of significant FFD events, industry-sponsored meetings, initiatives by the Nuclear Management and Resources Council (NUMARC) (now the Nuclear Energy Institute) and the Substance Abuse and Mental Health Services Administration (SAMHSA) (formerly the National Institute on Drug Abuse [NIDA]) and its Drug Testing Advisory Board, and current literature. The review indicates that, although the rule is fundamentally sound and provides a means for deterrence and detection of substance abuse, some matters need to be addressed. These matters include the—

(1) Need to ensure compatibility with changes made to the HHS guidelines;

(2) Reduction of burden on licensees while fulfilling the purpose of the rule;

(3) Need for a limited number of new requirements, e.g., to further reduce the potential for subversion of the testing process and to make clear that the appeal process applies to all persons covered by the rule; and

(4) Need to clarify the Commission's original intent in several areas to reduce incorrect or inconsistent use and differing interpretations and to make a number of administrative changes.

While none of the proposed amendments represent major changes,

they do represent modifications that would substantially reduce the cost of implementation to licensees; enhance overall program integrity, effectiveness, and efficiency; and help to ensure the continued protection of public health and safety.

Discussion

The proposed amendments take into account the experience gained in implementing the initial rule, developments in the FFD area, and actions by other Government agencies on drug testing and other FFD concerns. During implementation of new regulations, particularly regulations in rapidly evolving disciplines such as drug testing and employee reliability, a substantial number of lessons are learned from experience. The first five years of experience with the NRC's fitness-for-duty rule are no exception. A significant number of the proposed revisions are adjustments to the rule that would decrease the burden on licensees without reducing the protection of public health and safety afforded by the rule. For example, one proposed revision would allow licensees to grant unescorted access to personnel covered by another licensee's FFD program. This would facilitate interchange of employees in, for example, ''peer evaluator'' situations. Another proposed revision of this type would permit licensees to accept generic portions of training provided by another licensee to people covered by the rule. This revision would recognize that significant portions of all licensees' fitness-for-duty training cover the same general subjects and would facilitate more timely contractor support during outages.

While some proposed revisions would increase program efficiency, others would ensure that the Commission's FFD program more effectively achieves its objectives. For example, the Commission is proposing several revisions to the rule's drug and alcohol testing requirements that would clarify testing processes and purposes. While many of these rule changes would strengthen testing requirements, others would reduce the testing burden on licensee and contractor employees. These and other revisions would bolster the rule's protection of public safety while reducing the industry's regulatory burden where possible.

The NRC is also proposing a substantial number of revisions to respond to legal and regulatory changes that have occurred since the publication of 10 CFR Part 26. For example, the Department of Transportation (DOT) and its operating administrations (e.g., the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), and the Federal Highway Administration (FHA)) and other Federal and State agencies have expanded their drug and alcohol testing requirements during the past five years. Some of these regulatory changes have created requirements applicable to some licensee employees and contractors that duplicate the NRC's drug and alcohol testing requirements. To reduce unnecessarily duplicative burdens, the Commission is proposing to permit testing performed under these other programs to be accepted in lieu of 10 CFR Part 26 testing when individuals covered by an NRC program are also subject to another program. Another change since the publication of 10 CFR Part 26 has been the implementation of the requirements of the Americans with Disabilities Act (ADA). While the ADA specifically exempts the NRC's program from certain requirements, various proposed revisions to the regulation accommodate certain aspects of the Act. For example, the current rule requires licensees to determine whether unescorted access to protected areas and other activities specified in 10 CFR 26.2 have ever been denied to people seeking unescorted access because of substance abuse and related activities. This section would be revised to limit such inquiry to events that may have occurred during only the previous five years.

During the first years of FFD rule implementation a number of requirements have been found to be ambiguous and therefore subject to inconsistent application by licensees. These ambiguities have been costly to licensees and NRC staff as they have required a substantial number of discussions involving licensee FFD staff, attorneys, and consultants; NRC inspectors; and NRC headquarters staff. Although these ambiguities have already been clarified for many licensee programs, the NRC is proposing revisions that would clarify the Commission's intent and help ensure that the regulation is consistently implemented, inspected, and enforced throughout the industry. Increased consistency of rule application throughout the industry will benefit licensees and their employees by reducing the chances of arbitrary or discriminatory application of the rule.

Finally, there are a number of proposed revisions that would improve the clarity of the rule. For example, several terms regarding the testing process and testing results have been more carefully defined and consistently used to eliminate difficulties in interpretation.

In considering the actions to be taken, the NRC will continue to consider the proper balance between safeguarding an individual's rights and protecting public health and safety.

In proposing these FFD rule revisions, the NRC also notes that it is continuing to move toward a performance-based regulatory approach in most of its rule making. Performance-based regulations are intended to give regulated entities clear guidance as to the objective of those regulations but not to be overly prescriptive in mandating specific means by which those entities must achieve the objectives. In taking this approach, the Commission expects to promote efficiencies in nuclear facility operations while maintaining the highest standards of public health and safety. Both NRC policy and Congressional directives emphasize the need for the Commission to move toward performance-based regulation.

While some of the proposed FFD rule revisions reflect this performance-based philosophy—most notably the increased licensee discretion incorporated into § 26.80 auditing requirements—the somewhat prescriptive nature of the current 10 CFR Part 26 (particularly of Appendix A), and many of the proposed revisions, are a partial departure from that regulatory approach. The NRC believes that several characteristics of and issues associated with fitness-for-duty programs make it necessary for the Commission to continue to provide detailed directives in this particular context. A relatively more specific regulatory approach, for example, will continue to assure that state and local restrictions will not hinder the stringent drug and alcohol testing needed to assure that personnel covered by the rule will continue to safely and competently perform their duties. If the NRC's requirements are not clearly stated in the rule, some state and local laws would prohibit licensees from implementing key program elements, thus making complete achievement of the rule's performance objectives difficult or impossible. The NRC believes that it must maintain the specificity of this rule in order to clearly preempt such state and local laws that could otherwise apply to licensees' fitness-for-duty programs.

The rule's specificity also protects the rights of personnel subject to the rule's mandates. Many of the rule's detailed requirements address the need to assure that testing is performed in a highly reliable manner and that workers are not wrongly accused due to false positive test results. Many of these details address these concerns and have served to provide high confidence that false

positives will not be obtained. While protecting workers against unwarranted damage to their careers in this way, these detailed requirements provide quality controls that also assure accurate, valid, and dependable test results. This, in turn, bolsters FFD program credibility and acceptance among workers. The specific provisions in the rule have assured workers who do not abuse drugs or alcohol that FFD program requirements are administered fairly and competently and that their fellow workers who do violate FFD policy will likely be detected and removed from duty.

The rule's specificity has also benefited licensees during the first five years of the rule's implementation. This specificity has, for example, helped assure that positive test results can be more easily defended when challenged in court and during unemployment proceedings. They have also provided a clear statement of the NRC's position for licensees and labor representatives to use when negotiating FFD-related issues in collective bargaining agreements. The introduction of drug testing and related fitness-for-duty program requirements into the workplace is a mandatory issue for collective bargaining under the National Labor Relations Act. A prescriptive fitness-for-duty rule enables licensees and labor representatives to more effectively achieve the NRC's program objectives by clearly showing that the NRC requires particular program elements to be implemented in specific ways.

Like the NRC, other Federal and state agencies have also found it necessary to establish specific requirements rather than adopt a more performance-based approach to assuring worker fitness. For example, the detailed nature of the NRC's FFD rule is matched by the drug use and alcohol abuse prevention rules promulgated by the DOT and its five operating administrations. The level of detail of the HHS requirements for the testing of Federal workers is also comparable to that provided by Part 26. The experience of these agencies bears out the need for relatively specific regulations in this workplace fitness context.

The NRC seeks public comment on the following issues. Public comments should be submitted to the NRC as indicated under the heading **ADDRESSES.**

1. Would any of the proposed changes, group of related requirements (e.g., modifications to prevent subversion of the testing process, further ensure the accuracy and integrity of testing, clarify actions for removal), or the rulemaking as a whole provide a substantial increase in the overall protection of the public health and safety or the common defense and security? Are the groupings and subgroupings of the changes contained in the Backfit Analysis section of this Federal Register notice appropriate and are the changes categorized properly? Are the changes in Group III worthwhile and necessary to better accomplish the FFD rule's objective, clarify the rule's existing requirements, and reduce ambiguities. Does the rule as a whole not constitute a backfit since the rule's cumulative effect is to ease licensee burdens or leave them essentially the same, rather than to increase them. Does anyone subject to the rule not object to the new requirements in view of their perception of an overall benefit and, if so, would their non-objection be grounds for not applying the backfit rule? Although the NRC believes that the proposed specific changes to the fitness-for-duty rule (FFD) would be the most efficient method of accomplishing the regulatory objectives of the changes, are there any viable alternative approaches that should be considered, particularly with respect to the proposed changes in Group III B? Could the rule be less specific in stating the requirements? The staff's analysis of alternative approaches such as development of a Regulatory Guide, NUREG good practices, meetings with licensees, or industry initiatives, is contained in the draft Regulatory Analysis.

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

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

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

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

a. Including Ph and/or creatinine as well as SG in the required testing to determine specimen validity;

b. Requiring tests to determine specimen validity (which might include SG, Ph, and/or creatinine) immediately after specimen collection at all sites and immediate collection of a second specimen from those individuals providing specimens with abnormal qualities; and

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

6. With respect to the discussion of the proposed changes to Section 2.7 of Appendix A:

a. Should the NRC require tests for agents that can be added to urine as an attempt to mask THC (marijuana) or other drugs?

b. Should the NRC raise the cutoff levels for screening and confirmation

tests for opiates to reduce the laboratory-confirmed positives for opiates that the medical review officer (MRO) determines to be negative? Given the high level of concern for safety in the nuclear industry, should the NRC retain the current levels, even if HHS should raise the levels for ''demand reduction'' programs covered by its Guidelines as it proposed on November 16, 1995 (60 FR 57587).

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

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

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

8. The NRC has received requests from several licensees and vendors to permit the on-site use of non-instrumented, qualitative immunoassay methods that involve the use of inexpensive, disposable devices. As discussed in more detail under the proposed changes to Section 2.7 of Appendix A, these screening techniques have not been validated to achieve the high levels of specificity and accuracy that are needed in FFD programs. Of concern to the Commission is that these devices may produce an unacceptably high number of false negative test results and may be easily subverted. The Commission invites public comment on the advisability of creating guidelines, quality assurance procedures, and performance standards to govern use of these devices. Alternatively, should the Commission prohibit the use of these devices until such time as HHS (or another agency) has developed guidelines, procedures, and standards. Should there be a Conforming Products List for these devices similar to that published by the National Highway Traffic Safety Administration (NHTSA) for evidential breath measurement devices? Who should administer such a program?

Groups of Interrelated Revisions

Several of the proposed rule changes should be considered as groups of interrelated revisions that, if adopted, will interact with each other and with the current rule to accomplish important FFD objectives. Foremost among these are several revisions intended to minimize subversion of the testing process. Subversion has proven to be a continuing problem that threatens the effectiveness of workplace testing programs across the country. Although a number of techniques for subverting the testing process exist, flushing (diluting the specimen by drinking copious amounts of water) appears to be the most common. The proposed rule is intended to reduce the potential for successful subversion by flushing include (1) a requirement that licensees minimize the time between notification of the person to report for a random test and the collection of the specimen and (2) a requirement to determine the validity of specimens, which would be done through testing for specific gravity (SG) and may include several other methods. Other forms of subversion include the adulteration of specimens and the submission of surrogate specimens. Reducing the time between notification and testing will also counter these subversion techniques. To further reduce the potential for subversion, the NRC proposes using a narrower temperature range than set by the HHS guidelines for determining an acceptable specimen. This would make it more difficult to submit surrogate specimens and to use some dilution techniques. The proposed rule also would revise various sections to state more clearly that any act or attempted act of subversion is to be considered a violation of FFD policy. These revisions would provide an integrated response to the problem of subversion.

The Commission also is proposing to require that dilute and other questionable specimens be tested at the lowest level of detection (LOD) that the laboratory is qualified to use. While this revision would have an anti-subversion effect, its primary purpose would be to further protect those being tested. Currently, when a testing laboratory determines that a specimen is dilute or otherwise of questionable quality, the person tested is required to produce a second specimen under the direct observation of a collection site person. Test results indicate, however, that a great majority of dilute specimens result from reasons other than drug use. Requiring level-of-detection testing would infringe less on the individual's privacy by minimizing the need to produce a second specimen under direct observation. It would protect those being tested also by providing MROs with additional useful information to enable them to make accurate determinations of whether a specimen of questionable validity has actually been adulterated or diluted.

The proposed revisions pertaining to removal from unescorted access because of FFD policy violation and subsequent return to work constitute a second important group of interrelated revisions. One revision would clarify the Commission's original intent that any violation of a licensee's FFD policy must result in immediate removal from unescorted access status upon determination of a violation. Before a person is allowed to return to work, the condition that led to removal would have to be resolved through a medical determination of fitness conducted by appropriately qualified personnel and the person would have to be tested under a proposed return-to-duty testing requirement. Another related revision would clarify the Commission's intent that persons to whom unescorted access is reinstated after a policy violation are to be subject to follow-up testing for a three-year period. These and other proposed changes are intended to provide a more complete set of requirements relating to removals and return to duty.

The NRC is also proposing a set of revisions that would address situations in which individuals subject to the rule's testing requirements are only infrequently on site. Although most licensees have appropriate provisions in this area, several licensees have gone to great expense in bringing off-site workers to the collection facility for testing immediately upon their being chosen from the random testing pool. Some off-site workers have been required to drive 2–4 hours each way, fly cross country, and/or stay overnight. Some licensees use mobile collection facilities or teams to travel to the location of the person selected for testing. One proposed revision would make clear the NRC's original intent that people need not be immediately brought to the site for testing in such situations. Another related revision would eliminate the requirement for a suitable inquiry into a person's employment status when the person returns to a site after having not been covered by an FFD program for thirty days or less. This

revision would also clarify the requirements applicable to individuals who come to the site only infrequently.

A fourth group of revisions relates to testing for alcohol. Impairment caused by alcohol misuse creates a safety risk that is fundamentally similar to the risk posed by the misuse of illegal drugs. Some licensees, however, have imposed lesser sanctions for alcohol violations, an approach that is contrary to the Commission's intent. The NRC proposes to rectify this situation by explicitly requiring the same minimum sanctions for abuse of alcohol as currently exist for use of illegal drugs. Several proposed revisions would contribute to this objective. One revision would explicitly define the FFD policy violations involving alcohol. Likewise, alcohol test results between 0.02 and 0.04 percent would be forwarded to the Medical Review Officer (MRO) for back calculation to determine whether the person had an impermissibly high blood alcohol content while on duty. The requirements concerning conduct of suitable inquiries would also be revised to explicitly require that licensees determine whether persons seeking unescorted access status have ever used alcohol in a manner that resulted in on-duty impairment.

A fifth group of proposed revisions would address current ambiguities associated with the testing for the use of amphetamines. The standard for confirmatory testing for methamphetamines would be supplemented with the requirement that specimens must also contain a specific amount of amphetamine to be confirmed as positive. Multiple screening tests would be permitted to reduce the amphetamine testing problems caused by cross reactivity. A requirement that specimens confirmed positive for amphetamines must also be tested for d and l isomers is another related proposed revision. Another proposed revision would allow an extra two days for HHS-certified laboratories to report to licensees test results having suspected amphetamines. These revisions would serve to clarify and rationalize testing requirements for amphetamines.

Use of Old Test Results

The NRC also cautions licensees that test results obtained before January 3, 1990, should be considered with great care. The results may be questionable for the following reasons:

- The HHS laboratory certification program was initiated in 1988 and by the end of 1989 about 40 laboratories were certified. Many of the laboratories being used did not meet current performance standards for accuracy and reliability.
- In some cases, confirmation tests may not have been conducted.
- In many cases, there was no review by a technically qualified person, such as a MRO, to determine if legitimate uses of drugs (particularly amphetamines and opiates) were causing the results reported by the laboratories.

The NRC staff has been informed of several cases in which persons alleged they had a record of a questionably positive drug test 5 to 15 years ago, have since worked in the nuclear industry with a good work record and no positive drug tests, and are now denied employment. The Commission recognizes that positive drug test results obtained before the rule was implemented may indicate persons who have a significant past history of drug abuse but, because of the factors noted above, other available information should also be considered.

Description of Proposed Changes by Section

The following discussion describes the changes to the current FFD rule that are being proposed and the reasons for the changes.

Section 26.2 Scope

The NRC proposes to amend this section to include specified classes of personnel who administer testing programs. Although Section 2.3 of Appendix A requires that licensees carefully select and monitor persons responsible for administering the testing program based upon the highest standards of honesty and integrity, some licensees' testing programs have not included all persons originally intended to be tested. This action is taken to clarify the Commission's original intent because although these people normally work outside the protected area, their actions do have an ongoing effect on safety and would have an impact on the confidence of management and the workforce in the integrity of the program and the reliability of the results. Persons who administer testing programs are in a position to permit substance abusers to remain undetected. The persons who administer the tests could inadvertently omit testing of an employee as a result of impaired behavior on the part of the test administrator because of substance abuse or intentionally because of motives associated with substance abuse, empathy with the abuser, etc. Furthermore, the omission of test administrators from testing and other program requirements tends to undermine the credibility of licensees' FFD programs.

Several reported incidents have confirmed the need to assure that FFD program personnel meet the highest standards of honesty, integrity, reliability, and trustworthiness. For example, one licensee added collection personnel to the testing pool after investigation of an allegation determined that two specimen collectors were substance abusers. In another instance, a contracted MRO not in the testing pool was reported to be an alcoholic and an abuser of prescription drugs.

The proposed revision to § 26.2(a) would fulfill the NRC's original objective for this section and require all licensees to extend the coverage of their programs to the following three classes of FFD personnel:

- Personnel who can link test results with the person who was tested;
- Personnel making removal and return-to-work recommendations or decisions; and
- Personnel involved in the selection and notification of employees for testing and the collection of specimens.

Specimen collectors, the MRO, the FFD program manager, Employee Assistance Program (EAP) counselors, and other selected administrative staff would be examples of FFD program personnel who would be included within this clarification of the rule's scope. Testing of FFD personnel is further discussed in conjunction with Section 2.3 of Appendix A.

The NRC also proposes to amend § 26.2 to allow reduced scope programs for facilities that are in the process of being decommissioned. Because the level of risk associated with these facilities will decline during decommissioning, the revision is designed to provide the NRC with the flexibility to tailor the FFD program to site-specific factors as deemed appropriate by the NRC to protect public health and safety.

Finally, the NRC proposes to amend § 26.2 to provide that people covered by a program regulated by another Federal or state agency that meets the general performance objectives of the FFD rule need not be additionally covered by a licensee's FFD program. Duplicate testing and training requirements applicable to an appreciable number of individuals working at nuclear facilities have become an increasing problem as the Department of Transportation's drug testing requirements and new alcohol testing rule have been implemented. Differences in specific program requirements, such as the use of different cut-off levels (but which are at

least as stringent as the HHS guidelines), would be unlikely to have a significant effect on the licensee's FFD program in meeting the general performance objectives. The licensee would continue to be responsible for behavioral observation, immediate removal from duty of persons whose fitness may be questionable, and for-cause testing for a specific situation. This revision would reduce the burden on individuals covered by multiple Federal and State programs with requirements that duplicate the FFD rule.

Section 26.3 Definition

The NRC proposes that this section be modified to clarify definitions of some terms, to make terms and definitions more consistent with those used by other Federal agencies (including the Substance Abuse and Mental Health Services Administration and the Department of Transportation), to provide new definitions to support other sections of the rule, and to remove three terms, ''random test,'' ''follow-up testing,'' and ''suitable inquiry,'' because they are already fully defined in the text of the rule. In addition, several terms have been moved to this section from Section 1.2 of Appendix A because they first appear in the main body of the rule.

For the most part, changes in this section are intended to eliminate differing interpretations and ambiguities in current wording. The Commission proposes three changes to the terms used for definitions of drug test results. The changes include modification to the definition of ''confirmed positive test'' to reflect proposed changes to terms and definitions, and the addition of the terms ''laboratory confirmed positive'' and ''unconfirmed positive test result.'' ''Laboratory confirmed positive'' would refer to the positive outcome of a gas chromatography/mass spectrometry (GC/MS) test. These tests are reviewed by the MRO to determine if they show a violation of the FFD policy or if there is a medical explanation for the positive result. ''Unconfirmed positive test result'' would refer to the result of a screening test that is not negative. The original wording of the rule refers to these results in a number of ways, most often as ''presumptive positives.'' The term ''presumptive positive'' and other terms used to refer to this result have been replaced with ''unconfirmed positive test result'' throughout the rule to increase clarity and consistency. The definition of ''confirmatory test'' would be revised to reflect a proposed revision made elsewhere in the rule relating to blood tests for alcohol that could be used in an appeal. The term ''screening test'' would replace the former terms ''initial or screening test'' in the interests of clarity.

The NRC proposes to add a definition of ''medical determination of fitness'' to support proposed changes to other sections of the regulation. This term would clarify the role of the MRO or other licensed physician in determining fitness for duty and provide a standard regarding what constitutes this determination. The focus of the medical determination would be to determine if a rule or policy violation has occurred and to evaluate the potential for on-duty impairment (e.g., of sensory, cognitive, motor and communicative skills) that would interfere with the safe performance of the individual's duties.

A new definition of ''behavioral observation'' is proposed that would clarify the role of supervisors in monitoring the behavior of workers under their oversight. It is the NRC's intent that all personnel having unescorted access to the protected area be subject to behavioral observation. To accomplish this goal, supervisors are expected to observe the behavior of all personnel with whom they have routine contact, not only those workers for whom they have direct supervisory responsibility. Licensees would, for example, be responsible for ensuring that contractor employees whose supervisors may remain off site be subject to behavioral oversight by licensee supervisory personnel when within the protected area. The contractor employees would, however, still be subject to behavioral observation by their own supervisors when off site. A definition for ''supervisor'' is proposed to clarify that supervisors include all personnel with supervisory responsibilities over workers with unescorted access, whether they are on site or off site.

The NRC proposes to add the terms ''abuse of legal drugs'' and ''substance abuse'' and definitions for these terms to clarify the intent of the rule and to support changes to management actions and sanctions regarding alcohol and other legal drugs and substance abuse.

The NRC proposes to add the term ''subversion'' and to define it in terms of the intentional causing of a missing or inaccurate drug or alcohol test result at any stage of the testing program, including the process of selection and notification, specimen collection, specimen analysis, testing, and reporting of test results.

Finally, the NRC proposes that the definition of ''aliquot'' be modified by adding language designed to make it clearer that the aliquot is a representative sample of a specimen and can be used for retesting.

Section 26.7 Communications

A new section, ''Communications,'' similar to existing sections in other 10 CFR Parts would be added to ensure that communications with the NRC are processed properly.

Section 26.8 Information Collection Requirements: OMB Approval

The NRC proposes to delete § 26.8(c) which presents an estimate of the total time burden for this Part's recordkeeping requirements and solicits licensee comments concerning the accuracy of the estimate and ways by which the burden can be reduced. This information is not normally codified in the regulations and is being deleted to maintain consistency with other parts throughout 10 CFR Chapter I. Burden estimates and requests for public comments on the burden estimates continue to be published in the preamble of Federal Register Notices for NRC rulemaking in accordance with Office of Management and Budget (OMB) regulations.

Section 26.20 Written Policy and Procedures

The NRC proposes several changes to this section. One amendment would make it clear that licensees' overall description of their policy on FFD must be prepared in a summary form, which most licensees have done, and made readily available to employees covered by the rule [§ 26.20(a)]. It has been noted during inspections that a few licensees had incorporated their FFD policy into the several procedures that were not readily available to employees. The NRC's intent remains that licensees publish a statement notifying employees of the policy as is required by the Drug-Free Workplace Act of 1988.

Other amendments would clarify § 26.20 (a) and (d) to ensure that a licensee's FFD policy addresses employees' off-site involvement with illegal drugs, the abuse of legal drugs, the subversion of the testing process by adulterating or substituting specimens, the refusal to provide a specimen, and use of prescription and over-the-counter medications that may cause impairment. This revision would make explicit the need to address FFD concerns that have emerged during the first five years of program operation.

Another amendment would clarify the requirements pertaining to licensees' procedures to ensure that persons called in to perform an unscheduled working tour are fit to perform the task assigned [§ 26.20(e)]. This section currently

requires called-in employees to state whether they have consumed alcohol within the licensee's pre-duty abstinence period. The proposed revision would make it clear that this declaration of fitness includes fitness to perform tasks assigned, not just alcohol consumption. These revisions would afford employees an added safeguard in that they would have an opportunity to express their own opinion as to whether they believe themselves fit in view of fatigue, illness, use of medication or consumption of alcohol to perform assigned tasks. This requirement would also enable licensees to obtain the information over the telephone to avoid having to get that person safely home after arriving onsite unfit to work, call in another person, and avoid the potential for civil lawsuits that could arise from accidents while the called-in person is in travel.

Another amendment would remove the statement that the Commission may review the licensee's FFD policy and procedures at any time [§ 26.20(f)]. This provision is unnecessary because the Commission may always inspect the licensee's program.

A new § 26.20(f) would add a paragraph that would allow licensees to credit unescorted access status granted by other licensees. Such individuals must be covered by the random testing and behavioral observation programs of either the original licensee employer or that of the host licensee. This change would facilitate the interchange of personnel among licensees in, for example, situations where a ''peer evaluator'' from one licensee works with a second licensee (e.g., inspections conducted under the auspices of the Institute of Nuclear Power Operations (INPO)). It clarifies that there is no need for a licensee to audit another licensee's program before granting unescorted access to that licensee's employee.

The NRC continues to believe that an abstinence period of at least 5 hours preceding any scheduled working tour is appropriate and wishes to clarify the implications of this abstention period for employees. This requirement continues to accommodate a reasonable and moderate amount of off-duty alcohol consumption outside the abstention period. Employees do need to be aware, however, that immoderate alcohol consumption, even if it occurs before the start of the abstinence period, can later result in an FFD policy violation. If, for example, an employee were to consume a relatively large volume of alcohol six hours before starting work and, in the interim, consume a heavy meal (the consumption of food can significantly slow the metabolism of alcohol), the employee could be at risk of violating FFD policy (i.e., could have a blood alcohol content (BAC) of 0.04 percent or higher when reporting for work). Therefore, it is incumbent upon employees to exercise restraint in their alcohol consumption even outside of the 5-hour abstention period. Although moderate off-duty drinking is not prohibited by FFD policy, employees should understand heavy alcohol consumption can be an FFD concern even though it occurs before the abstinence period. The NRC is aware that some past alcohol-related violations of licensees' FFD policies have resulted from employees' lack of understanding of these issues. Communication of these matters to employees is particularly important because the proposed rule would make management sanctions mandatory for alcohol-related FFD policy violations.

Section 26.21 Policy Communications and Awareness Training

The NRC proposes to decrease the frequency of FFD policy and awareness refresher training from every 12 to every 24 months. However, the Commission expects that FFD program changes, such as would be mandated by final rulemaking, would be communicated to all affected workers before the changes are implemented. The material presented in this training is relatively straightforward and is not expected to change significantly over time. Refresher training on a nominal 24-month frequency would be sufficient to keep personnel covered by the rule aware of FFD program policy and procedures. Another proposed amendment to this section would allow licensees to accept the generic portions of training of individuals who have been subject to a Part 26 program at another site and have received initial or refresher training within the past 24 months; site-specific training would continue to be required before unescorted access may be granted. Policy communications and awareness training covers a number of common areas that are consistent across licensee programs. Because there are some differences among licensees, new personnel should be trained in those aspects of licensee programs that are particular to the site.

Section 26.22 Training of Supervisors and Escorts

The NRC proposes to amend the provision pertaining to the initial and refresher FFD training of supervisors and escorts. One amendment would clarify the NRC's intent that, except in the case of people receiving their initial supervisorial assignment, all supervisors of licensee employees and contractor personnel and all escorts must fully complete their initial FFD supervisory training before assignment to duties within the scope of Part 26. Supervisors of licensee employees receiving their initial assignment would be required to complete training as soon as feasible but would continue to have up to three months to complete initial training. Supervisors of contractor personnel receiving their initial supervisorial assignment would have only ten days to complete initial training. Given the higher rate of positive tests among contractor personnel, it is particularly important to ensure that contractor supervisors complete their training either before or very soon after they assume their duties. Although the NRC considered amending the rule to clarify requirements concerning situations in which contractor, and possibly some licensee, supervisors do not have unescorted access privileges themselves but supervise people who do have such privileges, it believes the following guidance should suffice. The NRC expects that those supervisors who do not come on site would be trained in drug recognition, behavioral observation, and procedures for initiating corrective action. The NRC also expects that, while on site, these workers are observed by someone trained in these matters.

The NRC is concerned that some licensees may have appointed people as ''acting'' supervisors for periods of less than three months and have given these people none of the programmatic training required by this section. The NRC believes that even ''acting'' supervisors must be trained in the five topics appearing in § 26.22(a) as soon as feasible.

The NRC is also proposing to allow a written examination that demonstrates an adequate knowledge of pertinent FFD issues and material to be used in lieu of refresher training for supervisors and escorts in two out of every three years. Allowing the use of a written exam would increase flexibility without compromising the integrity of FFD programs and may decrease administrative expenses. The NRC has declined to change the nominal 12-month frequency associated with this refresher training for supervisors and escorts as it proposes to do for the policy communications and awareness training required by § 26.21(b). Supervisors and escorts must, for example, be able to recognize drug use or degradation of performance of the

people working around them. Having training, or a written examination in lieu of training, at an interval of more than 12 months may not be sufficient to ensure that supervisors and escorts would remain diligent and effective in performing these functions.

Another proposed amendment would allow licensees to accept the training of people who have been subject to a Part 26 program at another site and have had initial or refresher training (or testing in lieu of refresher training) within 12 months before assignment to supervisory duties. This proposed revision would facilitate the movement of supervisory personnel among licensees and decrease licensee costs for training individuals in a number of common areas that are consistent across licensee programs. As noted previously, because there are some differences among licensees, new employees should be trained in those aspects of the licensee's program that are site specific.

As noted by the Commission's regulatory review group, behavioral observation training as described in § 26.22(a) should not focus solely on substance abuse. Instead, it should also provide managers and supervisors training in appropriate actions to take (e.g., referral to EAP) when individuals have FFD problems other than substance abuse that affect them (e.g., stress, fatigue).

Section 26.23 Contractors and Vendors

This section currently requires that personnel who have been denied access or removed from activities within the scope of Part 26 for violations of an FFD policy will not be assigned to activities within the scope of Part 26 without the knowledge and consent of the licensee. During the first five years of FFD program operations instances occurred in which personnel with a history of substance abuse known to the contractor employer were sent on site without the licensee being informed of such history. Therefore, this section is revised to make clear that persons with a known (to the contractor or vendor) history of substance abuse must not receive these assignments without the knowledge and consent of the licensee.

The NRC understands that some contractors have requested escorted access for individuals with a drug history in order to avoid informing the licensee. The Commission desires comments as to whether the rule should be revised so that this practice is no longer permitted.

Section 26.24 Chemical Testing

The NRC proposes to revise the descriptions of the four types of testing that are currently required. The proposed changes are intended to rectify inconsistent interpretations of testing requirements that have appeared across the industry during the five years of FFD program operations. In § 26.24(a)(1), chemical testing before granting unescorted access would be referred to as ''preaccess testing.'' It continues to be the NRC's intention that any test, whether before or after the beginning of a person's term of employment with the licensee, that is performed with the intent that it may be a test as required by § 26.24(a)(1) must meet the standards set forth in Part 26 and be reported to the NRC as a preaccess test. One proposed amendment to this paragraph designed to reduce unnecessarily redundant testing of applicants for access privileges, would allow licensees to consider any drug and alcohol test meeting Part 26 standards and performed within 60 days before the granting of unescorted access to serve as a preaccess test. A test performed by another licensee or under a testing program required by the U.S. Department of Transportation are examples of tests that would qualify as preaccess tests under this proposed revision. In such circumstances, the NRC would expect that licensees would use a dependable means of confirming that the person seeking access had actually been tested. This could be accomplished by the electronic exchange of pertinent information among licensees using a computerized data base that the industry is currently considering for implementation.

As another clarification of the NRC's original intent, as described in item number 4.5 of NUREG–1385, ''FFD in the Nuclear Power Industry: Responses to Implementation Questions,'' § 26.24(a)(1) would be amended to explicitly prohibit the granting of unescorted access until the person's negative preaccess test result has been obtained. However, another change would allow some relief from this requirement. Unescorted access could be granted before receipt of a negative test result if the person seeking access has no history indicating the use of illegal drugs or the abuse of legal drugs and has either had a negative result on a test meeting Part 26 standards performed within six months before the granting of unescorted access or been covered by a program meeting Part 26 standards for two consecutive weeks during that six-month period. This relief from the requirement to obtain a negative test result before the granting of access is based upon industry experience of the demonstrated reliability of workers who have been covered by a rigorous program in the past. In these circumstances, the NRC expects that licensees would confirm the occurrence of such tests or such coverage. These proposed revisions are intended to reiterate the importance attached to establishing an individuals' fitness status before unescorted access is granted. At the same time, these revisions would allow some efficiencies borne out by industry experience in the granting of access without compromising public health and safety. Some additional relief would be provided where the individual is transferring from another licensee. In this case, if the individual has been covered by an FFD program for 30 of the previous 60 days, no specimen need be collected and tested.

Other proposed changes to this section (§ 26.24(a)(2)) would more clearly describe the full meaning of the currently required attributes of random testing. Some licensees who randomly tested only during weekday day shifts provided predictable gaps in testing. People working during evenings and on weekends knew they would not be tested. Workers who were randomly selected for testing, but did not happen to be on site at the time scheduled for specimen collection because they normally worked off site or worked a night or weekend shift, were deleted from the list of people to be tested that day and other workers who were present substituted in their place. Thus, not all workers had an equal chance of being tested. All testing personnel and employees must be made aware that tests are truly random and unpredictable, and therefore that unannounced tests may occur during any day or night duty hours. Predictable patterns of random testing are prohibited by the rule. The proposed rule changes would create no new random testing requirements, but would instead clarify currently existing requirements that random testing be unpredictable and conducted at various times during the day. As discussed in item number 4.6 of NUREG–1385, which points out that HHS's ''Medical Review Officer Manual'' suggests that random sampling procedures should permit no ''safe periods'' for any employee: ''Each work day should present each employee with a new opportunity of having to produce a sample. * * *''

A provision would be added to clarify that reasonable efforts must be made to

test persons selected for random testing. For persons off site and within a reasonable traveling time and distance, the NRC expects collection of specimens be completed as promptly as notification and travel can be accomplished. For other persons selected for random testing, the NRC expects that upon their return to the site they be promptly notified and tested under the provisions of § 26.24(a)(2) and that the test would be recorded as a random test.

A proposed amendment would provide flexibility to conduct for-cause tests (§ 26.24(a)(3)) no more than 2 hours for the alcohol part of the test and 8 hours for the drug part of the test following an indicated need for testing. This change is intended to accommodate situations where no collection personnel are on site and need to be called in or the individual needs to be transported to another location for testing. While it is in the best interests of both the licensee and the worker in this situation to collect the specimens as soon as possible, as currently required, more flexibility is appropriate. A shorter time is specified for alcohol because of the more rapid metabolism of this substance.

Other additions to this section would be clarification of the conditions that initiate a for-cause test and clarification that an MRO or other licensed medical person must determine the fitness for duty of an individual tested for cause before that worker may return to duty. Although the NRC considered amending the rule to clarify requirements concerning situations in which a worker may be potentially impaired from causes that would not be detectable by drug and alcohol testing, it believes the following guidance should suffice. Although impairment caused by factors other than substance abuse is usually not a violation of the FFD rule by the worker, it is the responsibility of the licensee to assure that no impairment, regardless of cause, threatens public safety.

The NRC has received, but declined to adopt, recommendations that this section be revised to authorize licensees to administer an ''alcohol-only'' test in certain situations. Under this recommendation, only a breath test would be required when conditions that directly indicate alcohol use, such as alcohol on the breath, create a reasonable suspicion that the person may have misused alcohol in violation of the licensee's fitness-for-duty policy. The NRC believes that allowing an alcohol-only test in these circumstances would be inappropriate. It is preferable to perform both an alcohol test and a drug test, whether the alcohol test is positive or negative, to fully investigate the individual's fitness for duty. However, if the alcohol test is negative and the individual is determined fit by a designated licensee representative qualified to make the determination, the individual could be returned to duty pending laboratory testing of the urine specimen and receipt of urinalysis results. The Commission believes that this provides an appropriate balance between assurance of a thorough inquiry and determination of fitness and reduction of the impacts caused by time away from the work station.

The requirements pertaining to follow-up testing (§ 26.24(a)(4)) would be clarified by incorporating the provisions of § 26.27 (b) (4) to make explicit that all people to whom unescorted access is reinstated under § 26.27(b) must be subject to unannounced and unpredictable testing for at least three years following reinstatement. The duration of followup testing is supported by research which indicates that chronic abusers of alcohol and other drugs usually need several years to recover from their habits. Under these proposed amendments, licensees would be required to adopt a program that is tailored to the individual's medical history and that meets these minimum requirements. These amendments are intended to clarify the current conditions under which licensees can reinstate unescorted access following a first or second violation of an FFD policy. A proposed requirement that the testing be unpredictable is added to conform the followup testing to the existing requirements for random testing.

The NRC proposes to add a fifth type of required chemical testing referred to as ''return-to-duty'' testing (§ 26.24(a)(5)). In its current form, the rule does not clearly state the Commission's intent that licensees should test personnel having unescorted access when they return to work after extended absences. The NRC staff is aware that most, but not all, licensees are already testing people when they return to their sites after extended absences. The proposed new § 26.24(a)(5) would require return-to-duty testing when workers seek to regain unescorted access to protected areas in two types of circumstances. First, workers seeking to regain unescorted access after having been denied access under the provisions of § 26.27(b) would be tested and a negative result obtained before access is restored. Second, a worker who seeks to regain access at a particular licensee's plant after an absence from the possibility of being tested under that licensee's FFD program for more than 60 days would have to be tested under this requirement. Provisions are made in the rule to lessen the impact. This proposed revision is also intended to clarify expectations regarding individuals selected for random testing who are away from the site and not available for testing. The NRC staff understands that some licensees are currently calling people in for random tests from long distances (e.g., a 2- to 4-hour drive each way, cross-country flights, overnight stays). Some licensees use mobile collection facilities or teams to travel to the persons selected for testing. The NRC staff is also aware that many licensees are routinely testing people such as utility headquarters staff, contractors, and consultants who come to the site only infrequently but may have access status. The new return-to-duty testing requirements and the revisions to the pre-access and random testing requirements (§ 26.24(a) (1) and (2)) are intended to provide licensees the explicit flexibility to adjust their testing programs to eliminate unnecessarily ''heroic efforts'' to test.

The 60-day period was chosen in order to be consistent with the current preaccess processing standards in NUMARC 91–03, ''Nuclear Power Plant Personnel Access Authorization Data Exchange Guidelines,'' dated October 1992. The industry guidelines provide that to be issued a badge in a situation where an individual has an existing access authorization, the individual must either be currently covered by an FFD program including random testing, or have satisfactorily completed preaccess drug and alcohol testing within 60 days before badging, and be subject to a behavioral observation program and an FFD program. The industry guidelines also provide that the individual's activities should be checked if a licensee or contractor/vendor employee had been away from a licensee, or approved contractor/vendor, behavioral observation program for more than 30 consecutive days. The industry guidelines also provide that suitable inquiry should be updated if reinstatement of access is requested for an individual who has been away from an FFD program for a period of 30 days or more.

For workers who have been absent from the possibility of being tested under the licensee's program for more than 60 days, any drug or alcohol test meeting Part 26 standards and performed within 60 days before the granting of unescorted access could serve as the return-to-duty test. The returning worker would have to obtain

a negative test result before returning to work unless he or she has no history indicating the use of illegal drugs or the misuse or abuse of legal drugs and has either had a negative result on a test meeting Part 26 standards performed within six months before the reinstatement of unescorted access or been covered by a program meeting Part 26 standards for two consecutive weeks during that six-month period. As was adopted for preaccess testing, tests performed by another licensee or under a testing program required by the U.S. Department of Transportation are examples of tests that would qualify as return-to-duty tests under this proposed revision. In such circumstances, the NRC would expect that licensees would use a dependable means of confirming that the person seeking access had actually been tested or been covered by another program. This could be accomplished, for example, by the electronic exchange of pertinent information among licensees using a computerized data base that the industry is currently considering.

Various proposed editorial changes to § 26.24(d) would leave its requirements essentially unchanged from the amendment to this paragraph published by the NRC on August 26, 1991 (56 FR 41922).

The NRC is proposing a new paragraph (§ 26.24(e)) that would require that licensees keep to a minimum the time between notifying individuals to be tested and the actual collection of specimens. This requirement is intended to eliminate a significant vulnerability (time) in the testing process. Time is very important to persons attempting to avoid detection. Time enables them to flush themselves, obtain surrogate specimens, or obtain materials to dilute or adulterate their specimens. For example, an investigation was conducted to determine why two adjacent sites, drawing their workforce from the same geographic area, had significantly different positive rates for random tests. It was determined that different time intervals between notification and collection were the cause of the discrepancy. The licensee with the low rate had a 2-hour notification policy not vigorously enforced; the licensee with the higher rate had a 15-minute notification policy which it aggressively enforced. A DOT study showed an increase in the positive rate when there was little or no prior warning of specimen collection. Whereas ''normal'' random testing of motor carrier personnel was positive at a 2.5% rate, roadside stops produced at a 4.8% positive rate. In response to that experience, DOT revised its rule to require the person, upon notification, to immediately proceed to be tested. NRC inspections and surveys indicate that some licensees keep workers on the job and test them only at the end of a shift even though they have been notified that they are to be tested hours before. In other cases, licensees permit delaying tactics that result in lengthy periods between notification and testing. In both of these cases, alcohol can be metabolized below detectable levels and the person can flush himself or herself, to some degree, of drugs. Some licensees release workers for tests in a manner that allows them ample opportunity to obtain materials that might subvert the test results (e.g., adulterants or surrogate samples kept in a locker or vehicle). The NRC understands that operational necessity may prevent the tested person from reporting immediately and that being escorted between notification and test may be an unreasonable burden. However, several licensees have reduced the notification time by using the supervisor to coordinate the worker's availability for testing and withhold notification until the individual must proceed to the collection site. Licensees report that this approach does not cause any burden or inconvenience; it is merely a different way of doing things. One licensee reported that it escorted persons selected for random testing without giving them prior notice, which produced a low number of questionable specimens (NUREG/CR–5758, ''Fitness for Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports,'' CY 1994, Volume 5, page C–5). Therefore, the Commission expects that licensees will assure that opportunities for subverting the test are eliminated as much as is practicable.

Section 26.24(e) (paragraph (f) in the proposed rule) currently requires that MROs' review of test results be completed and licensee management notified of those results within 10 days of the initial positive screening test. The intent of this requirement is to ensure that results are obtained within a reasonable time after specimen collection. Industry experience has indicated in some cases that the current requirement is impractical. In order to make this requirement more effective across the industry, the NRC is proposing to require that MROs' review of laboratory test results be completed and licensee management notified ''as soon as practicable'' after specimen collection and no more than 14 days after the collection of a specimen. Because many licensees conduct on-site screening tests, the ''collection of a specimen'' standard would establish a more consistent and controllable time line than ''initial screening test.'' The licensees conducting initial screening tests on site would have the same amount of time to review the HHS-certified laboratories' reports as do those licensees not conducting onsite testing. Experience has shown that the majority of certified laboratories take only 1 to 3 days from receipt of a specimen to screen and confirm tests; isolated exceptions are usually caused by testing for 6-acetylmorphine (6–AM), formerly referred to as 6-monoacetylmorphine (6–MAM), and occasionally by unusual technical problems. The Commission believes that most test results should be known to an MRO within 5 to 7 days from specimen shipment to the laboratory. The Commission has no great concern where there is a legitimate technical basis for a short, reasonable delay by the laboratory, for example, where a specialized low-volume test, such as 6–AM, is done twice a week rather than every day. This revision would require, therefore, that MROs must advise licensee management of available test results and of the progress of the review if the review has not been completed within 14 days of the specimen collection. While slightly relaxing the test result reporting requirements, the NRC would still expect MRO reviews to be completed as soon as practicable, and, in accordance with a proposed clarification of Section 2.9(c) of Appendix A, that the MRO notify management immediately after the determination of a positive test result or other violation of FFD policy.

The NRC also proposes to clarify § 26.24(f) to require that the MRO must report all violations of the licensee's FFD program to management in writing and in such a manner that confidentiality is ensured. This requirement is also proposed as new paragraph (i) in Section 2.9 of Appendix A, which addresses reporting requirements and the review of test results. This provision is simply a clarification of existing practice and an adoption of a change made to the HHS guidelines in June 1994, and would not place a significant burden on licensees since it would require that only FFD program violations, rather than all test results, be reported in writing to management. Requiring that all determinations of FFD program violations be submitted in writing will assist in preventing reporting errors. Furthermore, although it is currently common practice to submit such

information in a manner that ensures confidentiality, the NRC believes that due to the sensitive nature of the information this provision should be explicitly required, as HHS does in its guidelines.

The NRC proposes to modify § 26.24(g) with several editorial changes to clarify requirements for performing screening, confirmatory, and blind performance tests at HHS-certified laboratories. These changes serve to clarify and explicitly state the currently existing practice by licensees. In addition, this paragraph and § 26.24(d) would require licensees to ensure that all collected specimens are tested and that laboratories report results for all specimen tests performed. This provision serves to clarify existing requirements, would be a companion to the change to § 26.24(f), and would be an adaptation of a change made to the HHS guidelines in June 1994, in which HHS required written reports on all specimens, both positive and negative, to ensure that all specimens had been tested and all results reviewed by the MRO.

The NRC is proposing to require that a confirmatory test for alcohol be performed if the screening test indicates a blood alcohol concentration of 0.02 percent or greater instead of 0.04 percent as currently required (§ 26.24(h)). In cases where the confirmatory test indicates a blood alcohol concentration between 0.02 percent and 0.04 percent, the result would have to be forwarded to the MRO for review and, if appropriate, back calculation (see new Section 2.9(h) of Appendix A). The purpose of this procedure would be to determine whether the tested person had a BAC of 0.04 percent or greater, indicating a violation of the FFD rule, at any time during the work shift.

Section 26.24(h) currently provides for a blood test to be administered if the tested person demands ''further confirmation'' of a positive confirmatory test for alcohol. The NRC is proposing to revise the regulatory language to better reflect the purpose of blood tests in that they would be used for providing additional information that could be considered during an appeal pursuant to § 26.28. Furthermore, licensees would be required to ensure that the blood specimen is drawn promptly after the confirmatory breath analysis. The result of the gas chromatography analysis of the blood specimen need not necessarily be measured against the alcohol cut-off level. Instead, the MRO should determine in these cases whether it is appropriate to extrapolate back in time to estimate the highest BAC that the worker had while on duty. In a related matter, the NRC desires data on the number of times blood specimens have been drawn and any instance where the BAC results were overturned. Approaches licensees have taken to maintain this capability and the associated costs would be useful for evaluation of possible future changes in this requirement.

In another revision to this section, the NRC is proposing a new paragraph (§ 26.24(i)) to address cases where an individual has a medical condition that makes collection of breath, blood, or urine specimens difficult or hazardous. The MRO, in consultation with the worker's treating or private physician, would be authorized to determine a method of specimen collection provided the methods chosen can achieve comparable results. The Commission anticipates that these occasions, which would include, for example, post-accident testing of an injured individual, would be extremely rare.

In connection with the blood tests which may be performed under § 26.24 (h) and (i), the NRC notes that the Occupational Safety and Health Administration (OSHA) has determined that some employees face a significant health risk as the result of occupational exposure to blood and other potentially infectious materials because the materials may contain certain bloodborne pathogens. OSHA published a final rule in the Federal Register on December 6, 1991 (56 FR 64004), that establishes requirements applicable to all occupational exposure to blood or other potentially infectious materials. This coverage appears to include personnel involved in the collection and handling of blood specimens collected pursuant to the NRC FFD rule. The OSHA rule requires employers that have one or more employees with this occupational exposure to take several measures to minimize the exposure. These measures include determining employees' potential exposure, establishing a written Exposure Control Plan designed to eliminate or minimize employee exposure, and taking various precautions to prevent contact with blood in the course of work. The NRC anticipates that licensees will evaluate their responsibilities under this OSHA rule.

Section 26.25 Employee Assistance Programs (EAP)

The NRC proposes to revise this section by replacing the permissive ''should'' with the mandatory ''must'' to clarify its original intent that licensees design their employee assistance programs to achieve early intervention and must provide for confidential assistance. While actually achieving early intervention in all situations where employees' problems could adversely affect on-the-job performance may not be possible, it is reasonable to expect that all licensees' EAPs be designed to achieve this goal and not include obvious impediments to early intervention. This would assure that self referrals are kept confidential and do not result in punitive action. The NRC wishes to emphasize that Employee Assistance Program staff shall inform licensee management when a person constitutes a hazard to himself or herself or others and that self-referral does not influence in any way the determination of an FFD violation.

Section 26.27 Management Actions and Sanctions To Be Imposed

The NRC proposes changes throughout this section to require the same sanctions for alcohol violations as currently exist for use of illegal drugs. Explicit sanctions were not contained in the original rule because the NRC wished to study the matter further. As a result of further study, the NRC concludes that impairment caused by alcohol abuse creates a safety risk that is fundamentally similar to the risk posed by the use of illegal drugs. Both types of abuse involve violation of explicit licensee policies, are unacceptable in the nuclear power industry, and should strongly be discouraged. Currently, licensees vary widely in their responses to alcohol abuse with sanctions ranging from a three-day suspension to termination. The FFD rule's lack of explicit minimum sanctions concerning alcohol has created problems for many licensees in negotiating and defending sanction decisions. Creating minimum sanctions for alcohol violations that are equal to those of illegal drugs will assist licensees in dealing with these situations while sending a strong message to workers about the risks involved in abusing alcohol. As discussed under the proposed changes to § 26.20, it is important for licensees to ensure that their employees understand the several factors related to alcohol consumption that could result in a violation of the licensee's FFD policy.

Section 26.27(a) would be revised to clarify certain aspects of the requirements for the written statement obtained from persons seeking unescorted access and for the conduct of suitable inquiries. In both cases, the revisions would require licensees to determine whether the person has a history of substance abuse or has previously violated a licensee FFD

policy. These changes are being proposed with the intention of requiring the gathering of more complete information on the backgrounds of applicants for unescorted access, particularly as to potential problems with the abuse of alcohol. In addition, the history, except for removal from activities within the scope of this part due to actions taken as the result of an FFD policy, would be limited to the last 5 years. It should also be noted that the proposed revisions are intended to ensure consistency between the suitable inquiry aspects of both the access authorization rule and the FFD rule and that one suitable inquiry for each worker should be sufficient to fulfill the requirements of the two rules. As in the Access Authorization program, ''best efforts'' requirements of § 26.27(a)(3) are accomplished through contacts with previous employers. In addition, fitness history need not be obtained for those covered by other programs or absent for 30 days or less.

The NRC has received recommendations that a standard form be available for all licensees' use in performing suitable inquiries into individuals' backgrounds as required by this section. The NRC will defer to licensees should they wish to develop and use this type of form.

There have been a few reports of instances where a contractor or vendor employee with concurrent unescorted access to several power reactor sites had tested positive and that information was not shared with the other licensees. Although the individual was denied access by the testing licensee, the unescorted access status was continued by the other licensees. The NRC considered requiring licensees to assure that such notifications are made or to make periodic checks with other licensees and contractor employers but believes that the licensees' procedures to implement the access authorization rule (10 CFR 73.56) should facilitate the sharing of the information.

Section 26.27(b)(1) would be revised to clarify several points. Applicants would be added to the types of people to be denied unescorted access if their fitness is questionable. Violations of FFD policy, such as refusals to test or subversion of the testing process, is added as a basis for denial. The successful resolution of the impairing or questionable condition has been added as a condition to assignment of duties, and a more systematic review of the fitness of all personnel being returned to duty whose fitness had been deemed questionable would be required. This action is being taken because there have been several instances in which licensees did not remove or delayed removal of workers whose fitness was questionable and ''automatically'' returned workers to duty without a test or adequate determination of fitness. Companion changes are proposed for § 26.3, concerning medical determination of fitness, and § 26.24(a), regarding for-cause and return-to-duty testing.

The NRC proposes various amendments to § 26.27(b) (2) and (3) [formerly one paragraph (2)]. The first amendment would more clearly specify that confirmed positive drug and alcohol testing determinations are to be considered violations of FFD policy. Another amendment would clarify that people who are suspended because of policy violation are still to be covered by the licensee's FFD program with respect to behavioral observation, chemical testing, and sanctions for violations and that a positive test result during the assessment or treatment period would constitute a second positive test. In a related matter, the NRC expects that, in those rare cases when an individual is randomly tested before the results of a previous test are known to the individual and both results are positive, the licensee will consider whether the second test result is likely to be the result of the use indicated by the first test and, if not, declare the second test to be a second positive and take appropriate action. As amended, this paragraph would also require that a person who is reinstated following a policy violation must successfully complete a return-to-duty test and be subject to subsequent follow-up testing.

Section 26.27 (b) (4) and (5) (formerly paragraphs (3) and (4)) would be revised to fully recognize the abuse of alcohol as an FFD violation. The NRC also proposes to revise paragraph (b)(5) to more directly express its intention that a person must be determined to be fit to safely and competently perform activities under Part 26 by an appropriate licensee manager and the MRO or other qualified physician before being returned to those activities. Like other proposed amendments to this section, these amendments would be intended to elevate the importance given to licensee decisions regarding unescorted access reinstatement following FFD policy violations.

Section 26.27(c) would be clarified so that the exact act that violated the FFD policy is recorded and provided in response to an inquiry. Subversion of the testing process would be added to the examples of violations that must be recorded and provided in response to a suitable inquiry. Each of these examples of employee activity would be a violation of the licensee's FFD policy. A new provision would require that any attempt to subvert the testing process must result in denial of unescorted access for a minimum of three years which would be consistent with the sanction required by § 26.27(b)(3) for a second violation of a licensee's FFD policy. This sanction was chosen because the NRC wishes to convey the seriousness of such acts. Lastly, paragraph (c) would be revised to allow licensees to dispose of records five years following denial of any access authorization resulting from the activity. These revisions would establish a basis for consistent minimum treatment of these violations across all licensee programs for employee activities that have resulted in varying licensee response during the first five years of FFD program operation.

The NRC also proposes to revise paragraph (d) of § 26.27 to direct licensees to treat NRC contractors similarly to NRC employees if a licensee believes an NRC contractor to be under the influence of any substance or otherwise unfit for duty.

The NRC is aware that the requirements of the American with Disabilities Act of 1990 (ADA) may have implications for licensees' compliance with the requirements of § 26.27. The employment provisions of the ADA, which became effective on July 26, 1992, require employers with 25 or more employees to protect disabled persons from discrimination in the workplace. People who have previously been addicted to drugs or alcohol but who have been successfully rehabilitated, or can demonstrate a successful period of abstention or negative test results, are among those that the ADA protects. It is the NRC's understanding that a person who has casually used drugs in the past but was not addicted to those drugs cannot claim the ADA's protection. The Act specifically excludes from its protection employees or applicants who are current users of illegal drugs. The Act also specifies that covered entities may require employees to comply with the FFD regulations of the NRC to the extent such employees are covered by these regulations (Sec. 104(c)(5)(B), Pub. L. 101–336, 42 U.S.C. 12114; see also 29 CFR 1630.16(b)).

The Equal Employment Opportunity Commission has published the Americans With Disabilities Act Technical Assistance Manual which somewhat clarifies the meaning of ''current use'' of illegal drugs. According to the Manual, ''current use'' is drug use that has occurred recently

enough to justify an employer's reasonable belief that involvement with drugs is an on-going problem. For purposes of taking an employment action, current drug use is to be determined on a case-by-case basis and is not limited to the day of use or recent days or weeks. Clearly, when determining whether a particular person is a current user of drugs, and therefore not eligible for ADA coverage, the required amount of time that must have elapsed since a person's last use of drugs must depend to a large extent on the nature of the particular employment context in which an employment action is being considered. This is confirmed by the Manual when it states that an employer may take an employment action against an employee with a history of illegal drug use if it can demonstrate that the individual poses a direct threat to health or safety because of the high probability that he or she would return to illegal drug use.

The NRC's policy, as reflected in 10 CFR Part 26, is that until a person can show that he or she has abstained from substance abuse for at least three years, there is a continuing probability of resumption of substance abuse that is too high, given the exceptional safety concerns of the nuclear power industry. This has been supported by medical evidence and clinical experience. Given the heightened safety concerns of the nuclear power industry, it is the NRC's view that a person is a current user and not a disabled person under the ADA because of drug or alcohol abuse until that person has demonstrated abstinence from substance abuse for a minimum of three years after a positive test. Even when considered disabled because of drug or alcohol abuse, a person covered by a program pursuant to 10 CFR Part 26 is by terms of the Americans With Disabilities Act still subject to the NRC's fitness-for-duty regulations.

Section 26.28 Appeals

The NRC is proposing amendments to the right to appeal granted by § 26.28. This section currently requires that people subject to the rule have an opportunity to appeal positive drug and alcohol test results. In keeping with revisions to several other sections that would be intended to counter testing subversion, an amendment would extend this right to appeal to all determinations of FFD violations.

The NRC proposes to clarify that the right to appeal includes applicants for unescorted access. The NRC understands that some licensees did not provide an appeals process to persons who tested positive on pre-access tests. The factors that could produce false positives among licensee employees and contractors (e.g., administrative errors, medical prescriptions) are equally likely to occur during pre-access testing of applicants for unescorted access. (Note that a change to § 26.24 will permit licensees to consider any test meeting the Part 26 standards as a pre-access test. Those standards include the appeals process under § 26.28, and apply to any test that the licensee plans to subsequently use as a pre-access test.) If applicants for unescorted access are not provided an appeals process, it is possible that some of them will be effectively barred from the industry based on test results erroneously determined as positive. Providing applicants an opportunity to appeal the validity of the test result would also enhance program credibility.

The NRC also proposes to clarify the contents and purpose of the notice to the individual determined to have violated an FFD policy, clarify that the review process must be objective and impartial, clarify that the individual may submit additional relevant information, extend appeal rights to applicants for access, and assure that relevant records are corrected if an appeal is successful. The NRC understands that, in some cases, the individual did not understand the purpose of the appeal process. The NRC also understands that, in many instances, persons responsible for the initial determination were conducting the review. The NRC believes that the effectiveness of the FFD program depends, to a large extent, on the perception by the workforce that the program is fair and worthy of their support, and that all reasonable efforts are being made to ensure that any decisions that could affect their careers are fair and based upon information that is complete and accurate and forms a sound basis for the decision. The use of even-handed, fact-finding procedures should ensure that incorrect determinations that could undermine the quality of a licensee's workforce and, thereby, be counter to the interests of safety, will not stand uncorrected.

As a related concern, the NRC has been informed that some licensees have required individuals to pay for the reanalysis of their specimen and the analysis of their split sample when pursuing appeals. Having to pay for the reanalysis can be expected to obstruct the individual's exercise of the right to appeal the licensee determination of policy violation as granted by this section. The NRC, therefore, considers requiring persons covered by the rule to pay for reanalysis of their specimen or analysis of the split sample to be inappropriate. However, requiring the person to pay after the fact should these subsequent tests also be positive would be an acceptable measure to control unwarranted appeals.

Section 26.29 Protection of Information

The NRC proposes to amend this section to clarify that contractors and vendors who legitimately seek information for unescorted access decisions by licensees are authorized to obtain this information. Contractors and vendors were unintentionally omitted from this provision in the original rule.

A second proposed amendment would allow disclosure of personal information collected in compliance with the rule to presiding officers of judicial or administrative proceedings that are initiated by the person who is the subject of the information. The purpose of this amendment would be to allow disclosure to, for example, state agencies investigating whether the firing of an employee was justified in order to determine unemployment compensation entitlements. This disclosure would be permissible as long as the subject employee initiated the proceeding.

Section 26.29(c) would be moved from current § 3.2 of Appendix A and amended to clarify that licensees must provide to the subject individual, upon written request, copies of all records pertaining to violations of FFD policy, including test results, MRO reviews, and management determinations pertaining to the individual. Some licensees have interpreted this section in ways that make it difficult for workers to obtain their records. For example, some licensees have allowed the tested persons to see the documents but have not provided them copies of the documents. This is particularly difficult in the case of contractor employees who may no longer reside in the plant area. These actions are contrary to the NRC's intent that persons covered by the rule have full and convenient access to documents pertaining to employment actions taken in response to the results of tests conducted under this rule.

Section 26.70 Inspections

The NRC is proposing to revise this section to clarify its intent that FFD service contractors must make available for inspection by duly authorized representatives of the Commission documents, records, and reports related to the FFD services they provide to licensee, contractor, or vendor FFD programs. In some instances, contracted service providers and testing laboratory

personnel have been reluctant to provide documents to NRC inspectors.

Section 26.71 Recordkeeping Requirements

The proposed amendments to this section would clarify the NRC's intent that licensees retain relevant records pertaining to determinations of FFD policy violations, not just records of confirmed positive test results. These records are to include those related to personnel actions following policy violation determinations (such as refusals to test and subversion of the testing process) as well as those pertaining to the testing process that detects the violations. This revised wording would clarify licensees' recordkeeping responsibilities as well as ensure that people covered by the rule would have sufficient access to documentation of personnel actions that can substantially affect their work status.

The proposed amendments to this section would also reduce the reporting frequency for program performance data from semiannually to annually and add the number of subversion attempts by type to reporting requirements to support the greater emphasis on subversion elsewhere in the proposed rule. The NRC has considered, but decided not to adopt, a recommendation that utilities with more than one site submit only a single semiannual program performance report for all sites. Such consolidation of data would prevent analysis of site specific performance and NRC inquiry into obvious inconsistencies such as large numbers of positive results at one site and no positives at the second or neighboring site.

Despite obtaining the FFD programmatic performance information that has been submitted pursuant to this section for the five years of program operation, the NRC believes that additional types of information could be useful in fulfilling its responsibilities of overseeing licensees' FFD programs and formulating public policy. As noted in the introduction to this notice, several parties have recommended that the NRC consider obtaining certain types of information in addition to those currently required by this section or now being proposed for inclusion under § 26.73. Such information could include the number and nature of grievances, arbitration proceedings, and lawsuits stemming from FFD-related issues; information related to licensees' EAP programs including types of services provided, whether such services are provided by licensee or contractor personnel, employee-to-counselor ratios, the number of personnel who are admitted to EAP programs by self referral and by supervisory referral, the reported and diagnosed problems, and overall results of EAP programs; and laboratory testing results that are being provided to MROs and what problems MROs are having in interpreting test results and making judgments as to whether FFD policy violations have occurred.

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

The NRC wishes to acknowledge the usefulness of lessons learned and program initiatives reported by many licensees that are summarized in NUREG/CR–5758 each year for licensees to consider and use to improve their programs and avoid common problems.

Section 26.73 Reporting Requirements

The current rule requires that licensees inform the Commission of significant FFD events and describes examples of significant events involving acts by licensed operators and supervisors that must be reported to the NRC. Item 10.1 of NUREG–1385 emphasized that the NRC expects licensees to exercise prudent judgment on whether or not unusual situations should be reported and that the significant events were not limited to the examples contained in the rule. However, the NRC understands that many significant events that would be useful for formulating public policy or that the NRC should respond to in a timely fashion have not been reported because licensee management decided not to report the event unless it was specifically required by the rule. Therefore, the NRC is clarifying that significant events are not limited to those listed and provides additional examples. One of the proposed amendments would add FFD program personnel, in keeping with clarifications to the scope of the regulation under § 26.2 (a), as a class of individuals whose improper acts would be reportable. Another proposed amendment would expand an example to include that any violation of FFD policy (e.g., possession of illegal drugs, refusal to take a test, attempt to subvert the testing process) by a supervisor, licensed operator, or FFD program personnel must be reported in contrast to the current example which describes reporting only confirmed positive test results.

Section 26.80 Audits

This section would be revised to permit licensees some discretion in conducting audits and to address a petition for rulemaking (PRM–26–1) filed on January 19, 1994. Rather than emphasizing compliance with a requirement to conduct an audit at a fixed annual frequency, licensees would be responsible for determining the appropriate frequency, scope, and depth of auditing activities within a 3-year period based upon a review of program performance indicators. These performance based audits would be conducted so that all program elements are adequately covered at least once during the 3-year period. In addition, the interval between audits of a program element would be relaxed to 36 months. The NRC is specifically interested in public comments on program performance indicators in addition to those contained in the text of the proposed amendment to the rule and whether they should be added to the rule or included in a guidance document. This relaxation of audit requirements would not be extended to contractors and vendors, whether they are implementing any portion of a licensee's program for their employees under the provisions of § 26.23, or providing contracted FFD services, such as specimen collection, testing, and MRO reviews. The amendments to this section would also clarify that licensees must continue to audit their HHS-certified laboratories on an annual basis.

The NRC recognizes that FFD is an evolving discipline and that new issues and problems will continue to arise. In some cases, turnover of FFD program personnel further exacerbates the problems. There is a frequent turnover in the contracted services, such as specimen collections, MRO reviews, and EAP services. Licensee audits have found many problems that were associated in some way with personnel changes. A proposed amendment to this section would require licensees to audit program elements that may potentially be affected by significant changes in personnel, procedures (e.g., specimen collection, testing, and MRO reviews

and reports), or equipment as soon as reasonably practicable but no later than 12 months after the changes. The purpose of these focused audits would be to assure that the change has not adversely affected the operation of the particular program element or function in question. One of the clear lessons of the early period of this rule's implementation during 1989 to 1991 was that licensees that performed early pro-active audits of their FFD programs were able to more easily and effectively correct programmatic problems and achieve effective program operations than those that waited the full nominal 12-month period before auditing their programs. Accordingly, this aspect of the performance based audit program would help ensure that whatever programmatic problems that may result from significant changes in personnel, procedures, or equipment will be detected and corrected on a timely basis.

Licensee audits of HHS-certified laboratories continue to find problems. In one case, the licensee's auditors had found sufficient problems in the first part of an audit to issue a stop-work order. The laboratory subsequently lost its HHS certification. Therefore, based on experiences gained to date, the NRC continues to believe that licensees must continue to audit at least annually the quality of contractor- or vendor-performed program elements, particularly when such activities are provided off site or are not under the direct, daily supervision of the licensee.

With respect to the petition for rulemaking, which was filed with the Commission by Virginia Power and assigned Docket No. PRM–26–1 on January 19, 1994, the petitioner requested that the Commission's regulations be amended to relax the existing mandatory audit frequency and require each licensee to audit its FFD program nominally every 24 months instead of nominally every 12 months with additional audits if performance warrants.

The petitioner requested the change based on its contention that the present requirement is resource intensive but of marginal importance to safety. The petitioner's further basis was that the industry's performance in ensuring a drug-free workplace has been very effective, the frequency and extent of auditing should be based on the need to assess performance, and that the licensees need increased flexibility to concentrate available audit resources in areas of observed weakness rather than mandatory audits of marginal safety significance. The petitioner stated that such a change would be consistent with audit requirements concerning operational safety, and that the blind performance test procedures and the quality controls required by Section 2.8 of Appendix A to 10 CFR Part 26 provide sufficient controls to ensure continued reliability and accuracy of the chemical testing. The petitioner indicated that its proposed change is not intended to preclude additional or more frequent audits if performance trends indicate additional overview is necessary.

The NRC believes that its proposed changes would go beyond that requested by the petitioner in that the interval for auditing the FFD program would be 3 years instead of 2, and the actual interval of the audits would be based more on need, as demonstrated by performance, than at a fixed interval. Therefore, adoption of the proposed change by the NRC would grant the petitioner's request with respect to audits of licensee programs. However, the NRC believes that licensees must continue to vigorously audit contractor/vendor-performed program elements, and has maintained the existing frequency of these audits.

The NRC understands that licensees have assumed that the term ''audit'' in Part 26 means a quality assurance (QA) audit that conforms to their normal audit program requirements and American National Standards Institute (ANSI) standards, such as ANSI N45.2, ''Quality Assurance Program Requirements for Nuclear Facilities,'' ANSI N45.2.12, ''Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants,'' ANSI N45.2.23, ''Qualifications of Quality Assurance Program Audit Personnel for Nuclear Power Plants,'' and ANSI N.18.7, ''Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants.'' The NRC does not require that these audits be performed by the QA organization in accordance with the QA program commitments for the conduct of audits. As stated in the current rule, the NRC expects that these audits must be conducted by individuals who are qualified (technically competent) in the subject(s) being audited and are independent of the program (to assure objectivity and no conflict of interest). At the licensee's option, the QA organization may perform, lead, or assist in these audits.

The following discussion describes the changes to Appendix A to Part 26 that are being proposed and the reasons for the changes.

Section 1.1 Applicability

Numbering changes to this section are being proposed to ensure uniform style and format throughout the rule.

Section 1.2 Definitions

Proposed changes to this section include deletions of defined terms that are either redundant with definitions in § 26.3, were moved to § 26.3, or are clear in the context of this Appendix. A proposed revision would define ''limit of detection'' (LOD) which is now used in the rule. Another proposed amendment would delete the term ''permanent record book.'' This change would make the Appendix consistent with recent amendments to the HHS guidelines and the Department of Transportation FFD regulations that eliminated the requirement for a permanent record book. Because HHS no longer requires a permanent record book, the NRC proposes to remove requirements for a permanent record book throughout the rule. The permanent record book was originally required based on the belief that such a book was necessary to ensure that critical information regarding collection and testing of each individual specimen was recorded. However, the FFD drug testing program specified in Part 26 requires that all information on individual tests be recorded on the chain-of-custody form and other forms and requires that all information related to determining violations be retained for five years. Therefore, there is no compelling need to maintain a separate longstanding record book. Eliminating this requirement reduces the regulatory burden on licensees and increases the efficiency of licensee drug testing programs (because the time taken to enter information into the record book while the testee waits is eliminated). The elimination of this requirement does not preclude licensees from making their own determination of the advantages of the use of a permanent record book and deciding to continue to maintain one. A definition of ''limit of detection'' has been added to support some of the several proposed changes intended to cope with subversion of the testing process and to protect individuals from incorrect allegations of such attempts.

Section 2.1 The Substances

The NRC proposes to amend this section to include return-to-duty testing and to clarify that when a licensee tests for any illegal drug during a for-cause test or analysis of a suspect specimen (currently permitted by the rule), the licensee may consider any detected

drugs or metabolites (as currently authorized in section 2.7(d) of this Appendix for samples suspected of adulteration or dilution). The NRC deems it appropriate, in these particular instances, where reasonable suspicion of an FFD problem exists, to allow close scrutiny at the discretion of the licensee. The licensee continues to be responsible for assuring that the results establish a valid basis for any action taken.

The NRC has given consideration to adding additional substances to the panel of drugs to be tested (e.g., benzodiazepines, barbiturates, and/or LSD) but has chosen not to add substances at this time. In the interests of developing and maintaining a coherent and well-organized drug testing program, the NRC anticipates continuing to follow the lead set by HHS in its guidelines. HHS reviews the panel of drugs from time to time from a national perspective. At this time, the NRC prefers to have any new additions to the minimum required drug panel dependent on HHS first adding substances to its panel of drugs to be tested. However, should the interest of public health and safety indicate a need to add substances to the drug panel, the NRC will take appropriate, timely action. The NRC continues to expect a licensee to consider any localized patterns of substance abuse when designing its FFD program, as required by § 26.24(c).

Section 2.2 General Administration of Testing

Section 2.2(a) would be amended to clarify 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. Licensees recently pointed out that current rule does not permit destruction of these records and that they have started to accumulate an appreciable volume of files. The retention of records for 5 years following termination of unescorted access would provide appropriate records for responding to background investigation inquiries while reducing the storage burden on licensees. Proposed modifications to section 2.2(d)(4) would clarify that the optional blood test for alcohol misuse is intended for use in a subsequent appeal of a confirmed positive alcohol test. By asking for a blood test, the individual is asking for information that can be used to appeal a licensee's determination of an FFD policy violation.

Section 2.3 Preventing Subversion of Testing

The proposed amendments to this section would clarify the individuals for whom appropriate background checks and psychological evaluations are required and would reduce the required frequency for those activities from every three years to every five years. These changes were made in response to licensee experience and for consistency with generally accepted security practices for reinvestigations into reliability and trustworthiness. This section also contains clarifications that would conform with proposed revisions to § 26.2 that would clarify the Commission's original intent that FFD program personnel responsible for the administration of testing would meet the highest standards for honesty and integrity and be under the drug and alcohol testing requirements of the rule. These additions specify that testing of FFD program personnel shall, to the extent practicable, be done by personnel independent of the FFD program. Rather than describe in the rule how this requirement should be implemented, the NRC recommends that the random selection process, specimen collection, and testing services could be considered for performance by licensee employees specifically qualified for these infrequent duties, persons under contract to meet this requirement, or an exchange of services arranged among sites or utilities in the same geographical area. Alternatively, if a licensee maintains FFD programs both on site and at corporate headquarters, the FFD personnel who administer the program at headquarters could administer the testing of on-site FFD personnel and vice versa.

This requirement is intended to reduce the possibility of FFD program personnel being responsible for testing themselves or their close colleagues. Unless otherwise specifically covered by the rule, personnel selected to test FFD program personnel would be independent of the administration of the FFD program to the extent practicable.

Section 2.4 Specimen Collection Procedures

The NRC proposes a number of changes in this section to increase the clarity and consistency in the wording of the rule. In addition to minor editorial changes, the NRC proposes to clarify that there is no requirement for the courier's signature to be included on the chain-of-custody form (§ 2.4(d)). Because specimens are sealed in packages that would indicate any tampering during transit to the laboratory, and couriers, express carriers, and postal service personnel do not have access to the custody and control forms, there is no need for such personnel to document the chain of custody for the package during transit. This is in keeping with standard forensic laboratory procedures and would streamline the specimen transportation process. This is also consistent with a recent revision to the HHS guidelines.

In regard to suggestions that the NRC specify actions to be taken if there is a break in the chain of custody, the NRC is aware that the Department of Transportation and HHS have published guidance that addresses the proper handling of breaches in the chain of custody in the transportation industries. The NRC believes this type of guidance is not necessary in the rule but expects that licensees would take action to discover and correct problems with the custody and control of specimens. Licensees should be aware that, when actual breaks in a specimen's chain of custody are detected and confirmed, the test result associated with that specimen must be invalidated. The NRC notes that judicial rulings indicate that minor ''administrative'' problems should not be considered breaks in the chain of custody. Examples include failure to include a middle initial or one digit of a social security number being incorrect, which are among the many techniques used in attempts by individuals to invalidate tests. Another ''administrative'' example found by the courts not to be a break in the chain is the collector and donor leaving a sealed specimen bottle unattended for approximately 1 minute with reasonable measures in place to conclude that no person had access during that period. This should not be interpreted to mean that the courts will accept sloppy collection procedures. The Commission expects that licensees will be sufficiently diligent and attentive to detail in this matter. The NRC would also note that licensees that test urine specimens for the five drugs specified in Appendix A to Part 26 at the specified concentration levels can use the OMB-approved Federal Drug Testing (chain-of-custody) Form (OMB Number 9999–0023) developed by the Department of Transportation and HHS and published in the Federal Register on August 19, 1994 (59 FR 42996). Licensees that test for additional drugs or use cutoff levels different than established by HHS in its laboratory certification program may not use the OMB approved form, but should use a ''look alike'' form.

That the collection site person shall note on the chain-of-custody form any

unusual behavior or appearance of a person being tested remains a requirement of Section 2.4(g)(9). The NRC has noted and considered the privacy considerations associated with this requirement and continues to believe that the need to take note of such behavior or appearance is an appropriate part of the testing process. Clarification to Section 2.4(f) would assure that a specimen of questionable validity would constitute a reason to believe the individual may alter or substitute a specimen.

In accordance with HHS Guidelines, the NRC proposes to eliminate the directive that tested individuals be provided an opportunity to set forth on the chain-of-custody form information concerning medications taken or administered in the past 30 days (Section 2.4(g)(4)). The availability of such information does not eliminate the need to do a confirmatory test on an unconfirmed positive screen test result. This information becomes useful only at the point at which the MRO reviews a confirmed positive test result. It is at this stage, when this information can be conveyed by the tested individual directly and confidentially to the MRO, that information about medications the person may be using or has used becomes germane to determining whether a fitness-for-duty policy violation has occurred. Eliminating the opportunity for the tested individual to provide this information on the chain-of-custody form would enhance the individual's privacy interests by precluding the chance of any testing program or licensee personnel other than the MRO learning of the individual's use of medication.

The NRC proposes to amend Section 2.4(g)(10) to allow licensees to have an individual, other than a collection site person, accompany an individual into a rest room not in the designated collection site if the designated collection site is inaccessible. The NRC also proposes to amend Sections 2.4(g)(15) and 2.4(g)(24) to allow licensees to have an individual, other than a collection site person, observe the collection of a specimen whenever there is reason to believe the individual may have altered or substituted the specimen. However, the requirement that the individual be of the same gender as the employee still exists. This proposed change is based on NRC's belief that it not always possible, under all circumstances, to have a collection site person of the same gender available. These revisions are consistent with the June 1994 changes to the HHS guidelines.

The NRC proposes reducing the required urine specimen quantity from 60 milliliters (ml) to 30 ml for the primary specimen and, when split specimens are collected, to require the collection of an additional 15 ml (Section 2.4(g)(11)). This change conforms with recent revisions to the HHS guidelines. Because some licensees conduct on-site testing and test for additional drugs, they may need to collect an additional volume to meet these needs. The NRC understands that laboratories require only a few milliliters for testing and that a 30 ml sample is sufficient in volume for both immediate testing and for the retention of a second aliquot for further testing, if necessary. The NRC also understands that accurate measurement of specimen temperature is difficult with a small volume but does not believe that ''partial'' specimens should be disposed of and not tested. Reported experience in other industries indicates that the consumption of water by those unable to give a urine specimen should be limited to one 8-ounce glass of water every 30 minutes but not to exceed a maximum of 24 ounces. This rate would protect the health of individuals who are providing specimens and is consistent with the recent revision to the HHS guidelines.

The NRC proposes changes to the collection procedures to ensure that a urine specimen is not adulterated or diluted and to detect surrogate samples being submitted. Licensees have reported several examples of specimens being adulterated or diluted and surrogate samples being submitted. This experience is consistent with that of other workplace programs discussed at HHS's Drug Testing Advisory Board meetings. These recommended changes reflect the NRC's desire to minimize the vulnerabilities in the collection and testing of urine specimens that substance abusers have exploited. In addition to limiting the time between notification and collection recommended in § 26.24(e), the first proposed change in the collection procedure in Section 2.4(g) would provide clearer guidance that an observation of a urine specimen for color and clarity be used to identify only obvious signs of adulteration (Section 2.4(g)(14)). Urine color and clarity are affected by a wide range of physiological changes including an individual's health, level of hydration, medications, and diet. Test personnel should therefore use observation of color and clarity of the specimen only for gross signs of adulteration. These may include crystals settled in the bottom of the container, off-colors such as blue or green, and an excess of bubbles when the container is shaken. The second proposed change (Sections 2.4(g)(13) and 2.4(g)(15)) would establish a narrower temperature band for acceptable urine specimens, with a minimum temperature of not less than 34°C/94°F (now specified in whole numbers in accordance with HHS guidelines). This should make attempts to submit surrogate samples more difficult and, together with other changes, would be consistent with practices by a few licensees that have produced good results. The third proposed change would allow licensees to set their own parameters, within the range set by the rule, of the accepted urine temperature range. This increased flexibility recognizes that there are a number of acceptable options for recording temperature and that each allows different minimum and maximum acceptable readings. For example, some temperature recording devices are located in the specimen container and record a ''peak'' temperature immediately. The temperature that is expected to be recorded by this device is close to core body temperature—a temperature that could occasionally require a second specimen under direct observation under the current rule. The current temperature requirement is based on a method that records the temperature several minutes after the specimen leaves the body. The range of temperatures (i.e., the spread between the minimum and maximum acceptable temperatures) must be limited as specified in the rule. The type of temperature reading device, and the acceptable range of temperature for that device, must be specified in the licensee's procedures. Two other proposed changes would reduce the likelihood of undetected tampering by requiring secure sealing of specimen bottles and, in accordance with HHS guidelines, shipment in tamper evident containers.

The NRC proposes two changes in this section with regard to testing for alcohol (Section 2.4(g)(18)). First, the NRC proposes to remove the requirement that the worker undergo a second breath test for alcohol when the first test is essentially zero (less than 0.01 BAC). The licensee may, at its discretion, collect and measure the breath a second time. This change reduces the impact on individuals being tested and on the licensee by reducing the amount of time taken by the testing process. It has been determined that a second negative test result is not

technically necessary. Second, the NRC recognizes that alcohol is metabolized relatively quickly (nominally 0.015 percent BAC per hour) and proposes to make explicit that the length of time between a confirmed positive breath test for alcohol and the drawing of a blood specimen to test for purposes of appeal must be minimized. This proposed amendment would require that the interpretation of the results of such a test must consider the time elapsed between the confirmed positive breath test and the drawing of blood for use in an appeal process.

Section 2.4(g)(24) [formerly (25)] would be revised to provide flexibility in internal reporting and actions when an individual fails to cooperate.

The NRC proposes making various revisions to the requirements for specimen preparation and transportation to the HHS-certified laboratory or to the licensee's testing facility to decrease the chance that specimens will be degraded between the time they are collected and the time they are screened and confirmation tested (Section 2.4 (i)). Reports from several licensees have suggested that specimen degradation during shipment has been the cause of ''false negative'' test results. The NRC has been advised that specimens not kept chilled during storage or transit may have become contaminated because of the buildup of bacteria and their wastes to an extent sufficient to possibly alter laboratory test results. Information on this phenomenon is limited and there are conflicting opinions regarding the seriousness of the problem. For example, one MRO stated that 19 of 21 on-site screening test positives were not confirmed because of degradation of the samples during shipment. (See Appendix B to NUREG/CR–5784.) Also, the reasons for unsatisfactory results of blind performance tests reported by the HHS-certified laboratories are that the blind specimens degraded below the cutoff levels or that the specimen containers adsorbed some of the drugs or metabolites. Therefore, the NRC has conducted pilot tests to gain additional insight on whether specimen degradation was a problem. These pilot tests detected a significant level of cocaine metabolite deterioration when urine specimens with a high relative acidity/alkalinity (pH) level were stored at relatively high temperatures (i.e., 100°F) for 36 hours or more. A modest study by one licensee showed a definite decrease in the concentration levels of THC in specimen bottles stored at room temperature for one week (e.g., from 199 to 178 ng/mL); where the specimen was allowed to touch the inside of the cap sealer, the concentration was reduced more than one half (e.g., from 199 to 77.8 ng/mL). The NRC specifically invites comments regarding the proposed revisions concerning specimen degradation and whether rule changes should be made or the information published in report form for voluntary use. In particular, the NRC is interested in data that licensees conducting on-site testing could provide. Of specific interest would be examples of on-site unconfirmed positives that had degraded during shipment. Licensees or other parties submitting such information should include any known factors, such as temperatures and duration of exposure to the suspect condition, that may have contributed to the problem.

At this time, the NRC proposes two specific revisions intended to address this specimen degradation problem. The first revision would continue to require that urine specimens be shipped to the HHS-certified laboratory within six hours of collection or cooled to not more than six degrees centigrade pending shipment (as previously required by 2.7(c)). The second revision would require that the time between specimen shipment and receipt of the specimen at the HHS-certified laboratory not exceed 48 hours, or that the time between shipment and the screening test at the HHS-certified laboratory not exceed 72 hours.

The NRC proposes several other minor editorial revisions to Section 2.4 in response to industry experience. These revisions do not substantially alter the intent of the original rule. Changes to Section 2.4(i) would simplify the tracking system for the courier and the laboratory. The NRC proposes that collection personnel should report incidents when an individual refuses to cooperate in the testing process to an appropriate authority (Section 2.4(j)), as designated by the licensee, rather than through the MRO to appropriate management. The NRC believes the MRO need not be a key player because refusals to cooperate are administrative concerns rather than medical problems.

Section 2.6 Licensee Testing Facility Personnel

A change conforming to the HHS guidelines is proposed to assure that training of licensee testing facility managers includes maintenance of chain-of-custody.

Section 2.7 Laboratory and Testing Facility Analysis Procedures

Proposed revisions to this section further clarify wording and procedures discussed in previous sections.

The NRC proposes several changes in this section that would be consistent with the recent revisions to the HHS guidelines. The NRC proposes to reduce the screening cutoff level for marijuana from 100 nanograms per milliliter (ng/ml) to 50 ng/ml (Section 2.7(f) formerly 2.7(e)). Current testing technology is capable of supporting reliable and valid results at this level. In addition, analysis of results in nuclear industry drug testing programs shows that positive test rates (indicating increased detection) increased substantially when the screening level was lowered to 50 ng/ml from 100 ng/ml. These proposed changes would make the NRC's FFD rule consistent with the HHS Guidelines (59 FR 29908; June 9, 1994) and the cutoff levels used by all other Federal agencies. This change is needed to ensure that licensees' specimens are tested by a process certified by HHS (any cutoff level different than the HHS-certified process must be accompanied by appropriate QA measures). The NRC proposes a revision to eliminate the requirement that test results be reported in batches (Section 2.7(h)(1)). In addition to being consistent with the recent revisions to the HHS guidelines and the current general practice, this would significantly decrease the amount of time required for licensees to receive certain types of test results from the laboratory.

The NRC proposes to clarify its original intent that licensees which retain split specimens must use a different HHS-certified laboratory in cases where a split specimen is being tested for an appeal (§ 2.7(k)). The NRC was informed by HHS that requiring a different laboratory essentially guarantees a different process for preparing the specimen which would provide a high assurance of detection of any laboratory error or inaccuracy of test results. In one instance, the same laboratory that produced a positive test retested the specimen during an appeal and, using the same method, made the same mistake and produced a second false positive test. The false positive was discovered in response to repeated appeals by comparing this laboratory's results with the results reported by another laboratory. Although suspected false positives have been extremely rare, this proposed revision would further reduce the possibility for recurrence of a false positive due to a laboratory error.

The NRC is proposing a number of revisions to this section aimed at enhancing the effectiveness and reliability of licensee FFD program by requiring testing to determine the validity of specimens; this adaptation of a recent change to the HHS guidelines would detect evidence of adulteration or dilution, thereby reducing the potential for subversion of the testing process. This change would also address concerns that the rule does not require the laboratories to report the results of tests, such as pH, specific gravity (SG), and creatinine, to the extent these tests are performed. Licensees have encountered various practices, such as adulteration and dilution, by substance abusers to avoid detection and the NRC desires to minimize the vulnerabilities in the testing process that have been exploited. One of these measures would be to determine specimen validity. Licensees conducting onsite testing would be required to determine the validity of all specimens collected; this would avoid disposal of specimens that would have been determined invalid by the laboratory. The validity of the specimens would be determined through the addition of testing for specific gravity on arrival of the specimens at the licensee's onsite testing facility or the HHS-certified laboratory (Section 2.7(e)). The NRC requests comments on whether these tests for determining specimen validity should include tests for acidity/alkalinity (pH), creatinine, and other tests for adulterants and whether these tests should be conducted as part of the collection process so that a second specimen can be collected immediately and under direct observation. To protect those being tested from incorrect conclusions about the validity of a specimen, the NRC is proposing that those specimens determined to be outside of specification would be subjected to both screening and confirmation tests at the limit of detection that the laboratory is capable of performing. The NRC understands that this may not be technically feasible for specimens containing some adulterants. In those cases, the laboratory would not test to limit of detection (LOD) and would report the specimen condition. The NRC understands that some HHS-certified laboratories have an LOD much lower than the established cutoff values, while others may not be able to achieve an LOD less than 40 percent of established cut off levels. Therefore, the NRC requests comments on the desirability of requiring that tests of specimens which are outside of specifications (i.e., show evidence of adulteration or dilution) be performed at the HHS-certified laboratory's LOD and depending on licensees to select laboratories capable of achieving the lower LODs and to develop appropriate quality controls. Recognizing the ability of HHS-certified laboratories to identify drug metabolites at lower concentration levels found in dilute specimens in a forensically sound manner, the NRC believes this is an appropriate approach to reducing the potential for incorrect conclusions about the validity of a specimen.

The NRC believes that the information developed during these procedures would enable the MRO to make an accurate determination of whether a specimen of questionable validity has actually been adulterated or diluted. If the specimen has been heavily adulterated or diluted, specimen validity test results would indicate an obvious attempt to subvert the testing process. If the specimen is moderately diluted, with no drugs detected, and the worker's health habits reveal consumption of appropriate quantities of liquids, the MRO would determine no attempt to subvert the testing process. If drugs are detected, the MRO would conclude that the worker has attempted to subvert the testing process.

In keeping with this proposed change to reduce subversion of the testing process, the NRC proposes to require (in Section 2.7(d)) that the Medical Review Officer report any adulteration or dilution evidence (excluding hydration resulting from an acceptable reason) to licensee management in order to enable licensee management to more vigorously pursue subversion attempts (Section 2.7(h)(1), formerly Section 2.7(g)(1)). Hydration resulting from acceptable reasons (e.g., drinking fluids for health reasons) would be excluded because this type of hydration occurs frequently, especially in warm climates. Another revision would add urine specimens that are determined on site to be questionable for adulteration or dilution to those specimens that licensees must ship to an HHS-certified laboratory for testing (Section 2.7(d)). By a related revision, all specimens that have been adulterated or diluted, or that the licensee specifies have been associated with personnel actions for other reasons, would be subject to long-term frozen storage for at least one year by HHS-certified laboratories (Section 2.7(i)). The NRC recognizes that these changes are minor clarifications or modifications to existing requirements and understands that many licensees are currently performing these proposed actions.

The NRC proposes four changes to the requirements for testing. First, the NRC proposes that a test for d (dextro) and l (levo) isomers of methamphetamine be required for all positive tests for amphetamines (an additional two days are provided the laboratory for processing specimens suspected of containing amphetamines) (Section 2.7(g)(6)). Some legal drugs (e.g., Vicks inhaler) contain amphetamine compounds that may yield a laboratory-confirmed positive for amphetamine use. Laboratory confirmatory tests for the d and l isomers are able to differentiate between compounds and to identify those positive test results that are the result of legal use. Many licensees have already been using this test as further confirmation of positive test results for amphetamines. This proposed revision would mandate the use of this test by all licensees and be consistent with current laboratory practice described by HHS in its Technical Advisory of March 11, 1991. Second, a new Section 2.7(f)(3) would permit multiple screening tests only in certain limited situations. This would adopt with some modification a 1994 change HHS made to its guidelines which is intended to be limited to amphetamines to reduce the effect of possible cross reactivity due to structural analogs, and to unique testing problems. However, a few licensees have expressed concern when they learned their laboratory was routinely using multiple screening tests on all specimens. Multiple screening tests should not be used on a routine basis because of the increased number of false negative test results that could occur. Third, the NRC is also proposing to reduce the time that licensees must wait for laboratories to provide testing results and, thereby, enable licensees to grant unescorted access to new employees and to conclude activities related to drug testing in a more timely manner (Section 2.7(h)(1)). It is the NRC staff's understanding that most HHS certified laboratories can, and usually do, report negative results to the licensee within 24 hours of receipt of specimens. A laboratory-confirmed positive result usually requires another 24 to 48 hours. Exceptions are when a positive test result for amphetamine requires further testing for d and l isomers or an opiate positive requires further testing for 6-acetylmorphine (6-AM) at a few laboratories. The reduced period of time provided to laboratories to report results assures that licensees will receive results in a timely manner and will reduce the time that new employees will have to wait for their unescorted

access, thereby reducing costs to the licensee. Fourth, the NRC proposes to require that a methamphetamine confirmatory test result contain at least 200 ng/ml of amphetamine for the result to be reported as a laboratory positive (Section 2.7(g)). This revision would conform with a similar change made to the HHS Guidelines on June 9, 1994 (59 FR 29908). This requirement was adopted by HHS to prevent false positive methamphetamine results that can be caused by chromatographic resolution problems in the confirmatory testing process.

In a related matter, the NRC understands that a significant percentage of laboratory-confirmed positives for opiates are determined to be negative by the MROs based on use of prescription medication, poppy seed consumption, no clinical evidence, or other reasons. In several public meetings, MROs and other FFD program personnel have expressed concern that the current opiate testing levels are not properly targeting opiate abusers. The concern is that the program is not effective in deterring or detecting heroin use (the rule requires clinical signs of abuse for the MRO to determine the test result as positive, yet heroin is frequently smoked or inhaled leaving no clinical signs of abuse), and large numbers of laboratory confirmed positives for opiates are determined negative, which imposes an unnecessary burden on the MROs and costs to the licensees. Data from eight licensees summarized in Table 3.12 of NUREG/CR 5784 indicate that only 2 of 124 laboratory-confirmed opiate positives were confirmed by MROs as positive (both of these positive results were reported by one licensee). These data are consistent with anecdotal reports from HHS and DOT officials and MROs.

The NRC understands that the Department of Defense (DOD) has raised its screening test cutoff level for opiates to 2,000 ng/ml and the confirmatory test cutoff levels for morphine to 4,000 ng/ml, codeine to 2,000 ng/ml, and 6-AM (a metabolite specific for heroin) to 10 ng/ml.

The NRC is specifically interested in public comments and supporting data as to whether it should raise the cutoff levels for screening and confirmation tests for opiates. Should the NRC set its levels consistent with those set by the DOD and proposed by HHS on November 16, 1995 (60 FR 57587)? Given the level of concern for safety in the nuclear industry, should the NRC retain the current levels?

Two revisions related to the short-term refrigerated storage of specimens are also being proposed (Section 2.7(c)). This section currently requires that specimens that do not receive a screening test within seven days of arrival at the HHS-certified laboratory be chilled in secure refrigeration units. The NRC has determined through pilot experiments that at least one drug metabolite is subject to deterioration if a urine specimen containing this metabolite is allowed to stand for more than 32 hours at relatively high temperatures. The NRC has also become aware of anecdotal evidence that indicates that, when specimens are shipped or stored at warm temperatures, there is a potential for drug or metabolite deterioration such that specimens containing drugs or metabolites over the cutoff level at the time they were submitted can be found to be negative in either screening or later confirmatory tests. The NRC is, therefore, proposing to require that specimens that will not receive a screening test and, if appropriate, a confirmatory test within one day of arrival at the HHS-certified laboratory be stored in a chilled condition until tested.

The NRC proposes several modifications that would clarify or modify requirements in light of industry experience. These modifications do not significantly affect the rule's original intent and are intended to reduce unnecessary problems in the implementation of the rule. First, Sections 2.7 (f)(1) and (g)(2), formerly Sections 2.7(e)(1) and (f)(2), would be modified to clarify that licensees using lower cutoff levels are not required to perform two different tests at different cutoff levels. Instead, they are expected to use extrapolation techniques to provide the required estimates of the number of positive test results from HHS-certified laboratories that would have occurred using the NRC cutoff level. Second, the NRC proposes to delete the requirement that licensees have emergency power equipment available for refrigeration units in the event of a power outage (Section 2.7(c)). Instead, the proposed revision would require only that licensees have some kind of contingency measures available to maintain specimens in a chilled state. Third, the NRC proposes to allow routine administrative tasks now assigned to the MRO to be performed by the administrative staff of the MRO (Section 2.7(h)(2)), formerly Section 2.7(g)(2). Licensee experience has found that the duties of the MRO are extensive and that many of the duties prescribed in the rule could be performed equally well by the MRO's staff without compromising the privacy of individuals. Fourth, the NRC proposes to make explicit that licensee contracts with HHS-certified laboratories provide that the licensee and the NRC should be able to obtain from the laboratory all information and documentation that is reasonably necessary for the licensee's inspection or audit of the laboratory, including, but not limited to, copies of the laboratory's HHS certification results (Section 2.7(n), formerly Section 2.7(m)). In addition, this revision provides for reduced licensee inspection activities in those areas currently inspected under the HHS certification program. Fifth, the NRC proposes to add to Section 2.7(n) a provision that would permit, in the event that a licensee's HHS-certified laboratory loses its certification, the licensee to use for up to 3 months an HHS-certified laboratory that has been audited by another NRC licensee that shares the same drug testing and cutoff standards. In such cases, the licensee would be required to audit the newly contracted laboratory within three months. Sixth, the NRC proposes to revise Section 2.7(h)(5) (formerly Section 2.7(g)(5)) to clarify that the laboratories, which are now required to provide expert testimony covering drug test results, would retain the originals of the specimen chain-of-custody form in order to assure that evidence is available for appeals. The documents would be retained by the laboratory consistent with the proposed retention requirements in Section 2.2(a) of the Appendix. Seventh, the NRC proposes to clarify the original intent of Section 2.7(k) (formerly Section 2.7(j)) with regard to the applicability of the quantification of test results to split specimens. In a related matter, the NRC considered but decided not to adopt a change to Section 2.7(h)(3) to further clarify that the laboratory must provide quantitation of test results to the MRO when requested. Some laboratories have been reluctant to provide such requested information. Eighth, the NRC proposes to clarify that the individual must be informed of his/her option to test the split sample (Section 2.7(k)). Inspections have indicated that, for various reasons, not all individuals are so informed. Ninth, the NRC proposes to make explicit that all standards 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 (Section 2.7(p)(2), formerly Section 2.7(o)(2)). The NRC has received comments from licensees regarding the receipt of out-of-date calibration standards for alcohol breath analysis

and regarding the inability of some screening test equipment to test at required levels. The NRC is also aware of the deliberate use of expired calibration standards.

The NRC also proposes to revise Section 2.7(k) by requiring an individual's request that his or her split specimen be tested in a timely manner. Current wording of the rule does not establish a time limit for an individual to request a test of a split specimen. The proposed revision would permit licensees to establish a definition of ''timely,'' but it could not be restricted to less than 72 hours from the time the individual is notified of the violation. Although recently revised HHS guidelines established a maximum time limit of 72 hours, the NRC believes licensees should be provided the flexibility to determine appropriate time limits for split specimen testing requests that meet particular demands associated with the licensee's notification experience (e.g., notification of result occurring just before a long holiday period or the individual out sick). This revision would also ensure that individuals' rights are protected by establishing the minimum 72 hour period within which they may make a request for split specimen analysis.

A proposed revision to Section 2.7(p)(3) (formerly Section 2.7(o)(3)) would allow use of alcohol breath analysis equipment that conforms to the September 17, 1993, amendments to the National Highway Traffic Safety Administration's (NHTSA) Model Specifications for evidential breath testing devices originally published in 1984. While these amendments reflect new lower evaluation thresholds for devices to measure breath alcohol, licensees need not acquire new devices that meet these amended standards. Breath analysis equipment that meets the 1984 NHTSA standards will continue to be acceptable in NRC FFD programs.

The NRC considered a potential revision to test for agents used to mask the presence of THC and other drugs. An analysis of specimens producing negative screening tests to assure that they do not contain agents that mask the presence of THC and other drugs could be specified by rule. Products that can be added to urine as masking agents are currently available and tests for these products are currently used by some laboratories. Testing for these products would increase the detection of attempts at subverting the testing process. While it has decided not to propose this revision at this time, the NRC invites public comment on both the need for and the resource impact of such a requirement.

The NRC has received requests from several licensees and vendors to permit the on-site use of non-instrumented qualitative immunoassay methods that involve the use of inexpensive, disposable devices. Convenience and speed in obtaining results appear to be the main advantages of these devices. Such testing does not use laboratory analysis techniques, can be performed quickly, and can produce virtually immediate results. These compact and portable testing devices show promise as a quick and easy method for testing in certain circumstances such as physician's diagnostic needs when the presence of drugs or alcohol can affect what treatment is suitable for emergency-room patients. These testing devices may also be well adapted to some criminal justice applications, roadside testing, or testing in remote locations. They are generally able to identify the five drugs or drug metabolites of concern to the NRC.

While Part 26 does not currently preclude the use of such non-instrumented devices for screening tests, the NRC is aware that there are several technical variables involved in the use of these devices that may prevent them from achieving the high levels of specificity, accuracy, and repeatability demanded in licensees' FFD drug testing programs. Temperature and barometric pressure can alter the amount of urine being tested and the repeatability of the test. Temperature variations may affect the reactivity of the chemical reagents and indicator strips being used. These effects alter the amount of urine being tested and the repeatability of the test. The NRC's concern is whether these types of technical variations will have sufficient impact to alter the specificity, accuracy, and repeatability of the test results. The NRC is concerned that the use of such devices may lead to a number of false negative screening test results. (The concern for false positive screening test results is minimal since all positively screened specimens must be tested at an HHS-certified laboratory and any positive results from the laboratory followed by a review of the results by an MRO.) The Commission believes that the use of testing devices that might increase the number of false negative screening test results is not consistent with the goals of FFD testing or to the credibility of the program to those subject to testing.

The NRC is also concerned that there are not sufficient procedural safeguards currently in place that would ensure reliably accurate screening test results if these non-instrumented devices were to be used by licensees. There are, for example, no quality control procedures known to the Commission that could be used to validate the results produced by the use of these devices, nor is there any mechanism in place to validate industry-wide results over time. For example, accurate tests at the beginning and end of a batch of specimens tested with an instrumented test would indicate all specimens in the batch were accurately tested. On the other hand, ''batch'' testing with these non-instrumented devices is probably not feasible. Likewise, the potential for subversion that could be introduced by the use of these devices has not yet been adequately investigated or addressed. Requirements may need to be developed to protect an employee's right to privacy and to minimize the chances for subversion of the testing process. No procedural safeguards exist in the text of the rule or in Appendix A that would address opportunities for subversion of the testing process which may be created by the use of these new devices.

Given the uncertainties surrounding the potential use of non-instrumented testing devices, the NRC would prefer that these devices not be used for screening tests in licensees' FFD programs at this time. The NRC is aware that HHS has been mandated to investigate the accuracy and reliability of these devices. The NRC will monitor the HHS investigation and continue to pursue its own inquiry into the feasibility of the use of these devices for FFD screening tests. As part of this effort, the NRC will determine whether new guidelines, quality assurance procedures, and performance standards that would govern their use should be added to Part 26.

To aid in this effort, the NRC invites public comment on the advisability of its creating guidelines, procedures, or standards for non-instrumented testing devices. The NRC would welcome specific recommendations as to how Part 26 could be amended or other means that would address the concerns discussed above and other issues surrounding the use of such devices. Alternatively, the NRC invites public comment on the advisability of its waiting until procedures or standards governing the use of non-instrumented testing devices are developed by other agencies and then evaluating and adapting those standards to the nuclear power industry's requirements. Should there be a Conforming Products List for these devices similar to that published by the NHTSA for evidential breath measurement devices, and who should administer such a program? The NRC

also would be interested in learning under what conditions, if any, would the use of non-instrumented drug testing devices produce cost savings as compared to licensees' current means of screening.

The NRC notes that Section 2.7(h)(4) (formerly Section 2.7(g)(4)) requires that HHS-certified laboratories transmit drug test results to MROs in a manner designed to protect the confidentiality of that information. In order to promote the efficient administration of FFD programs, it is the Commission's policy that FFD program personnel can assist MROs in the receipt and processing of the laboratory reports. While some programs have chosen to require that test results be received only by their MROs, others have allowed other program personnel under the supervision of an MRO to receive the results and forward them to the MRO. The NRC believes that both approaches are acceptable as long as the procedures for receiving and handling test results within the program are designed to preserve the confidentiality of the test results and actually accomplish that purpose. The NRC reiterates that a test result reported as a confirmed positive by an HHS-certified laboratory must not be considered a violation of a licensee's FFD policy until such result is reviewed by the MRO to determine if it constitutes evidence of such a violation. Therefore, the procedures through which the MROs receive test results from HHS-certified laboratories should contain explicit safeguards against improper disclosure of the report and premature actions such as the laboratory-confirmed test result being recorded in the employee's personnel file, an employment action being taken, or licensee management being notified of the positive result until after the MRO has determined that there is not an acceptable medical explanation for the positive result.

Section 2.8 Quality Assurance and Quality Control

A proposed revision to Section 2.8(b) would clarify that the current requirement that licensee testing facilities ''process'' blind performance specimens means that licensees conducting on-site testing must perform an immunoassay test on all such performance specimens before they are submitted to the HHS-certified laboratory. This revision is intended to make clearer the NRC's original intent regarding this requirement. A further revision would make explicit the requirement that licensees must evaluate the results of their HHS-certified laboratory's testing of the blind performance test specimens and a sampling of specimens screened as negative submitted by the licensee and take corrective action as appropriate.

The NRC, after consulting with SAMHSA, proposes an adaptation of recent changes to the HHS guidelines for blind performance test specimens (Section 2.8(e)). As HHS did with its guidelines, the modifications would reduce the percentage of blind performance specimens, reduce the proportion of blind performance tests relative to the total number of tests submitted, and reduce the maximum required number of blind performance test specimens. These changes are intended to ensure that the number of blind performance test specimens required to be submitted are adequate to assure quality in the testing process and particularly in the HHS-certified laboratory.

The NRC proposes to reduce the percentage of blind performance tests from 50 percent to 20 percent for the initial 90-day period and from 10 percent to 3 percent after the initial period, consistent with changes made to the HHS guidelines and the Department of Transportation's rules. The maximum number of blind performance test specimens required to be submitted both in the initial 90-day period and after is also lowered in the proposed revision. However, the NRC believes a maximum number less than that established by the HHS guidelines would assure adequate quality in the testing process. Whereas HHS lowered the maximum number of blind specimens to be submitted during the initial 90 day period from 500 samples to 200, the NRC proposes a further reduction to 100 specimens. The maximum number of specimens submitted thereafter during each quarter was reduced from 250 to 100 by HHS; NRC proposes a further reduction to 25 blind specimens per quarter.

Because the NRC permits on-site testing and very few specimens with unconfirmed positive test results would be submitted to laboratories at these sites, the NRC, in consultation with SAMHSA, proposes that there should be a minimum number of blind specimens (10 per quarter is recommended) to ensure that a sufficient number are submitted to assure the quality of the testing process.

The NRC intends that utilities with multiple collection sites submitting specimens to the same HHS-certified laboratory meet the percentage requirement for each collection site. However, a licensee may combine the number of specimens collected from its multiple sites to meet the total minimum requirement for all collection sites. That is, if one or more of the utility's collection sites and the corporate office contract with the same laboratory, they may pool their number of regular test specimens to meet requirements for the minimum number of blind performance test specimens. The NRC expects that blind specimens will be submitted to the laboratories from each collection site and that submission will be uniformly distributed throughout each quarter to correspond with the submission rate for other specimens.

The NRC also proposes to lower the percentage of blind performance test specimens which would be blank and raise the percentage which would be positive for one or more drugs (Section 2.8(e)(3)). Increasing the percentage of positive specimens would help offset the reduction in the minimum percentage requirements for blind performance test specimens and would assure that an adequate number of positive performance tests for each drug are submitted for quality control. Also, the NRC proposes that 10 percent of the positive blind specimens be appropriately adulterated or diluted and ''spiked'' to 60 percent of the cutoff value to challenge the laboratory's ability to determine specimen validity as proposed in Section 2.7(e) of the Appendix.

The third proposed revision would clarify that licensees must investigate any testing errors or unsatisfactory performance identified throughout the testing process or during the appeals process (new Section 2.8(f), formerly Section 2.8(e) (4), (5), and (6)). The NRC intended, in the original rule, that testing or process errors discovered in any part of the program, including the appeals process, be investigated as an unsatisfactory performance of a test. Thorough investigation and reporting of such test results will continue to assist the NRC, the licensees, HHS, and the HHS-certified laboratories in preventing future occurrences.

The NRC also proposes to clarify Section 2.8(e)(2) by modifying the reference to ''the initial 90-day period of any new drug testing program'' to read ''the initial 90-day period of any contract with an HHS-certified laboratory.'' The clarification would help assure that intensified quality testing is performed during the initial phase of testing by any new laboratory, as originally intended. (See previous discussions in item number 10.5.6 of NUREG–1354 and item number 4.15 of NUREG–1385.)

The NRC proposes revising Section 2.8(e)(1) by clarifying the criteria that

licensees must follow when purchasing blind quality control specimens. Currently requirements only ensure that blind quality control materials be purchased from labs certified by HHS or a HHS-recognized certification program. Due to the fact that not all suppliers of blind quality control materials adhered to uniform standards for preparation and certification, unacceptable blind quality control specimens have been used. These unacceptable blind quality control test results, e.g., false negatives or false positives, lead to increased costs and lowered efficiency because of additional tests and follow-up actions necessary to validate the results of previously tested actual specimens. More importantly, the unacceptable results may tend to cause loss of confidence in the testing process. In order to eliminate these problems, the NRC proposes to explicitly state the criteria, as HHS did in its recent revisions to its guidelines, in order to clarify for licensees the standards for blind quality control materials and make the rule consistent with existing practice.

Section 2.9 Reporting and Review of Results

The NRC proposes a number of revisions to this section to clarify the original intent of the rule.

Section 2.9(d) requires the MRO to determine if there is clinical evidence of opiate abuse before verifying a test result to be positive for that drug (meaning a clinical examination of all persons whose specimen was reported by the laboratory as positive for morphine or codeine). The NRC has become aware that some MROs believe that the opportunity for an individual to discuss a positive test result and related matters in a telephone conversation rather than at a face-to-face interview is sufficient to comply with this section. Providing the opportunity for only telephone conversations in some situations may not be adequate, particularly in cases where opiate use is in question. FFD experience demonstrates that personal, face-to-face, contact between the MRO and the subject individual can play an important part in arriving at fair and defensible judgments as to whether a violation of FFD policy has occurred. This process will be further clarified in the near future by HHS through revisions to its Medical Review Officer Manual.

The NRC proposes to clarify that the standards applied to the determination of whether clinical evidence of opiate abuse exists would include a range of evidence, including substantial evidence of lack of reliability and results inconsistent with ingestion of food or medication. Some MROs have interpreted this section of the regulation as restricting the types of evidence they should consider (Section 2.9(d)), in some cases resulting in ''pro forma'' rejection of all laboratory positives for opiates.

With regard to legal drugs, the NRC proposes to remove the requirement that Medical Review Officers determine whether there is clinical evidence of unauthorized use of over-the-counter and prescription drugs (Section 2.9(d)). This requirement has created difficulties for Medical Review Officers because there is little guidance that can be developed regarding what constitutes clinical signs of abuse for these substances.

The NRC notes that during the first five years of program operations, there has been programmatic inconsistency in MROs' decisions concerning the abuse of legal drugs, such as the use of drugs prescribed for one's spouse. This inconsistency has resulted in significant variance in management actions taken in response to this type of drug use. The NRC is not proposing a revision to this section. Instead, the NRC expects MROs to use prudent judgment in dealing with those situations which raise significant FFD concerns.

The NRC proposes clarifying that a medical determination of fitness be conducted (Section 2.9(g)) in the following cases: (1) Where there is a reason to believe that on-duty impairment may exist (whether or not there is an FFD policy violation), (2) in the evaluation of all for-cause tests results, (3) before making return-to-duty recommendations, (4) before granting unescorted access to the protected area when a record of a prior FFD violation exists, and (5) if a history of substance abuse is otherwise identified. The licensed physician or Medical Review Officer is to report to licensee management both determinations of FFD violations and determinations of any condition under which an individual may not be able to safely and competently perform his or her duties. These requirements are intended to increase assurance that a medical evaluation is performed for circumstances where fitness may be questionable. The NRC wishes to emphasize that the determination of an impairment problem that does not constitute an FFD violation must not result in punitive action toward the individual.

The NRC proposes to require Medical Review Officers to review BAC readings between 0.02 percent and 0.04 percent and to extrapolate the results of breath analysis for alcohol, or GC analysis of blood, back in time when appropriate (Section 2.9(h)). This would ensure that individuals who can reasonably be concluded to have had a BAC at or above 0.04 percent while on duty will be found to be in violation of the FFD policy.

The NRC proposes to revise Section 2.9(e) by clarifying what constitutes a ''timely'' request by an individual that an aliquot be reanalyzed. This would be an adaptation of the timeliness standard for testing split specimens recently adopted in the HHS Guidelines. However, under the HHS approach the split specimen ''belongs'' to the donor and the primary specimen ''belongs'' to the employer; therefore, the HHS guidelines are silent on timeliness for reanalysis of the primary specimen. Current wording of this paragraph in the NRC's rule requires an MRO to authorize a reanalysis of the original aliquot on the timely request of the individual tested. This ambiguity could be problematic for licensees who must determine how ''timely'' such a request actually is. The proposed revision would permit licensees to establish a definition of ''timely'', but it could not be restricted to less than 72 hours from the time the individual is notified of the violation. The NRC believes licensees should be provided the flexibility to determine appropriate time limits for requests for retesting specimens that meet particular demands associated with the notification of the worker (e.g., notification occurring just before a long holiday period or extended illness), yet this revision would also ensure that individuals' rights are protected by affording them a minimum of 72 hours within which they may make a request for reanalysis of the specimen. In addition, the NRC is allowing licensees the flexibility to dispose of test results, based on scientific insufficiency, after three years.

The NRC proposes adding a new Section 2.7(p)(6) and amending Section 2.9(b) by restricting the types of arrangements that can exist between the MRO and the HHS-certified laboratory or the operating contractor of an on-site testing facility. The NRC proposes to require that the MRO not be an employee, an agent of, or have any financial interest in the laboratory or on-site testing facility operator for which the MRO is reviewing drug testing results. Similarly, the laboratory and on-site testing facility operator shall not have any relationship with the MRO that may be construed as a conflict of interest. These restrictions are consistent with recent changes to the

HHS guidelines and the NRC believes that they will assist in eliminating any conflict of interest between the MRO and the contract laboratory and on-site testing facility operator that may affect the impartiality and objectivity of the MRO in reporting testing deficiencies or errors to licensee.

Section 3.2 Individual Access to Test and Laboratory Certification Results

The NRC proposes to delete this section and incorporate relevant portions of it as Section 26.29(c).

Section 4.1 Use of HHS-Certified Laboratories

The NRC proposes to add a caution, upon the advice of SAMHSA, that the HHS certification process applies only to the drugs and cutoff levels specified by HHS and that the defensibility of the results of tests at more stringent cutoff levels than those required under HHS guidelines, for analyses of blood specimens for alcohol, and tests for substances other than the 5 covered under HHS guidelines depends on appropriate measures by licensees to assure that the reported results are valid.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection and paperwork requirements.

The proposed rule will relax existing information collection requirements and will contain new information collections. The overall effect will also reduce existing information collection requirements, and the overall public burden of this collection of information is expected to be decreased by 170 hours per year per site. These estimates for both reduction and addition to burden include the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the collection of information contained in the proposed rule. Comments to the OMB on the collection of information or on the following issues must be submitted by June 10, 1996.

1. Is the proposed collection of information necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments regarding these burden estimates or any other aspect of this collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T–6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0146), Office of Management and Budget, Washington, DC 20503.

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed rule. The analysis examines the benefits, cost savings, and costs of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies may be obtained from Loren L. Bush, Jr., Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC, telephone (301) 415–2944.

Regulatory Flexibility Act Certification

In accordance with the Regulatory Flexibility Act of 1980, (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants and activities associated with the possession or transportation of Category I material. The companies that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the size standards adopted by the NRC on April 11, 1995 (60 FR 18344—10 CFR 2.810).

Backfit Analysis

This proposed rule would modify a prior Commission position by adding new requirements and reducing other requirements. The modifications are intended to improve the effectiveness of the rule in the light of demonstrated program performance and lessons learned since the implementation of the rule and to enhance overall program integrity. Some of the modifications would be made to make the rule consistent with modifications to the national standards on drug testing promulgated by the Department of Health and Human Services. Other modifications are intended to prevent subversion of the testing process (examples include: limiting the time between notification and testing, using a narrower temperature range to make it more difficult to submit a surrogate sample), further ensure the accuracy and integrity of testing (examples include: determining specimen quality, using a narrower temperature range, and requiring timely shipping and testing of specimens to prevent degradation of specimens), clarify actions for removal and return to service, incorporate advances in technology (example: measures to eliminate ''false positives'' from legitimate use of amphetamines), and protect individual rights.

The proposed changes are, for the most part, minor program adjustments or clarifications and do not alter the Commission's original intent. Furthermore, the modifications would better achieve the level of assurance in the accuracy of results and the integrity of the testing process which was originally intended. The NRC believes that some of the changes are needed to minimize the vulnerabilities that are being exploited by substance abusers.

To facilitate public consideration of these proposed changes, the Commission has placed the proposed rule changes into the three groups appearing below. The first group consists of those changes intended to conform the rule to the HHS Mandatory Guidelines that have been modified since the rule was last revised. Subgroup IA lists those changes intended to make the NRC rule compatible with the HHS Guidelines as revised. Because the Commission continues to desire to permit more stringent programs than set forth in the HHS Guidelines, it was necessary to adjust some of the new HHS requirements to meet the needs of the nuclear power industry. These are listed in subgroup IB.

The second group consists of those rule changes that would reduce licensees' regulatory burden. Subgroup IIA lists those changes in this category for which the Commission was able to calculate specific monetary savings to licensees. Some of the proposed changes in the second group would provide licensees with FFD program administrative flexibility that would provide some indeterminate reduction in burden. These changes are found in subgroup IIB.

Group III contains several proposed revisions that the Commission believes to be worthwhile and necessary to better accomplish the FFD rule's objectives. Subgroup IIIA consists of those proposed revisions that are particularly important to achieving the rule's objectives. These include revisions designed to reduce the incidence of subversion of drug and alcohol testing and to enhance the rule's protection of the rights of workers subject to the rule. The proposed changes appearing in subgroup IIIB would serve to clarify the rule's existing requirements, reduce ambiguities that have often resulted in interpretative debates, and make other administrative changes. Some of the Group III changes, such as establishing a more restrictive temperature range, would result in a departure from the HHS guidelines.

Whether the proposed changes would, considered as a whole or individually, provide a substantial increase in overall protection of the public health and safety is a significant question. NRC staff is of the preliminary view that these changes, although desirable, would not provide a substantial increase. Public comment is specifically requested on this question of substantiality.

If the Commission were unable to conclude at the final rulemaking stage that these changes would provide a substantial increase in overall protection, the further question arises whether the rule should nevertheless go forward. One approach to continuation of the rulemaking would be to view the rule as a whole and to conclude, if warranted, that the rule's cumulative effect is to ease licensee burdens or leave them essentially the same, rather than to increase them. This would be consistent with an interpretation that the backfit rule does not apply to relaxations of requirements. However, the mandatory nature of the proposed rule, and effects on interested persons other than licensees, could present complicating factors. Alternatively, the question is presented whether those subject to the rule would decide not to object to the new requirements in view of a perceived overall benefit and, if so, whether non-objection could be grounds for not applying the backfit rule. The basis here would be that the backfit rule was solely directed at controlling objectionable impositions of additional requirements. Public comment on these considerations is specifically invited.

LIST OF PROPOSED CHANGES TO 10 CFR PART 26

Group I: Adoption of National Standards

A. Changes To Ensure Compatibility With the HHS Guidelines as Revised in June 1994

§ 26.24

(f) MRO to report FFD policy violation in writing.

(g) Ensure all collected specimens are tested and results are reported.

Section 1.2 of Appendix A

- Delete definition of permanent record book

Section 2.4 of Appendix A

(d) Courier signature not needed on chain-of-custody documents.

(g)(4) Eliminate requirement that tester request list of medications prior to specimen collection.

(g)(9)+(24) Eliminate the requirement for a permanent record book.

(g)(10)+(15)+(23)+(24) Allow accompaniment or observation by person of same gender, other than a collection site person.

(g)(11) Clarify fluid intake to assist in providing specimen.

(g)(13) Specify the temperature range for an acceptable urine specimen in whole numbers.

(i) Clarify requirements concerning use of second, tamper-evident shipping container.

Section 2.6 of Appendix A

- Assure training of licensee testing facility managers includes maintenance of chain of custody.

Section 2.7 of Appendix A

(f) Lower the cutoff level for marijuana screening tests from 100 ng/ml to 50 ng/ml.

(g) Modify the criteria for determining that a specimen is positive for amphetamines.

(g) Require testing for d and l isomers of amphetamines.

(h) Eliminate batch reporting of results.

(p) Laboratory shall not have a conflict of interest with licensee's MRO.

Section 2.8 of Appendix A

(e) Require blind quality control materials meet standards for preparation, certification, and stability.

Section 2.9 of Appendix A

(b) MROs shall not have a conflict of interest with certified laboratories.

Section 4.1 of Appendix A

(b) Note that licensees need to take appropriate measures when testing outside HHS certification process.

B. Changes To Conform HHS Guidelines Revisions to the Framework of the Original FFD Rule

§ 26.24

(d)(1)+(g) Require licensees to ensure that all collected specimens are tested and results reported.

Section 2.4 of Appendix A

(g)(11) Reduce required minimum quantity of each urine specimen from 60 ml to at least 30 ml (Where licensee chooses to test on site, split specimens, or to test for additional drugs, more than 30 ml will be necessary).

Section 2.7 of Appendix A

(e) Validity of specimens, i.e., tests for adulteration and dilution at HHS laboratory.

(f) Permit multiple immunoassay (screening) tests for the same drug or drug class.

(k) Clarifications to split specimen collection and dispatch procedures and laboratory selection.

(k) Minimum time for requests by individuals to have split specimen tested at another HHS laboratory.

Section 2.8 of Appendix A

(e) Reduce the maximum number and percentage of blind performance specimens to be submitted per quarter but require a minimum.

Section 2.9 of Appendix A

(e) Minimum time for request by individual for reanalysis of original specimen added.

Group II: Reduction in Burden

A. Changes With Quantitative Monetary Benefits

§ 26.2

(f) Eliminate duplicate testing under multiple programs.

§ 26.20

(f) Credit for unescorted access status granted by another licensee.

§ 26.21

(b) Refresher training intervals extended from 1 to 2 years.

(b) Acceptance of generic portions of training provided by another licensee.

§ 26.22

(c) Acceptance of generic portions of training provided by another licensee.

§ 26.24

(a)(1) Flexibility in pre-access testing

—Tests within past 60 days may be considered pre-access tests if they meet the standards of Part 26

—Access may be granted pending test results for individuals covered by an acceptable FFD program for 2 consecutive weeks in the past 6 months

—No pre-access test for those transferring from another program who have been covered by an FFD program meeting the requirements of Part 26 for 30 of the past 60 days.

(a)(2) Persons off site and unavailable when chosen for random testing may be tested when next on site.

(a)(3) People tested for-cause for alcohol can return to duty while awaiting urinalysis results.

(a)(5) Clarify existing testing requirements for persons unavailable for testing for short periods and insure consistency with the access authorization program.

(e) Limit time between notification and specimen collection.

§ 26.27

(a) Fitness history need not be obtained for those covered by other programs or absent for 30 days or less.

§ 26.71

(d) Reduce frequency of program performance reports.

§ 26.80

(a) Change to performance based audit as the basis for reducing required frequency.

Section 2.2 of Appendix A

(a) Permit prompt destruction of chain-of-custody forms showing negative test results.

Section 2.3 of Appendix A

• Extend reinvestigation interval for FFD program personnel from 3 to 5 years.

Section 2.4 of Appendix A

(g)(18) Eliminate second breath specimen when test shows no alcohol.

Section 2.7 of Appendix A

(e) Test questionable specimens to level of detection.

(h) Permit MRO staff to perform certain support functions.

(n) Eliminate need to audit areas covered by HHS inspections.

B. Changes That Provide Greater Flexibility and Indeterminate Monetary Benefits

§ 26.2

(e) Reduce requirements during decommissioning.

§ 26.22

(c) Refresher training intervals may be extended from 12 to 36 months if written exam is given every 12 months.

§ 26.24

(a)(3) Provide flexibility in timeliness of for-cause test.

(f) MRO to complete review as soon as practicable and inform management if determination of test result is delayed more than 14 days after collection instead of completing review and notifying within 10 days after screening test.

(i) Flexibility for unusual medical conditions.

§ 26.27

(a) Certain aspects of fitness history to be limited to 5 years.

(a) Power reactor licensees usually need not obtain statements responding to activities related to possession or transport of Category I nuclear material.

(c) Allow records of FFD violations to be discarded after 5 years.

§ 26.29

(b) Permit provision of personal information for judicial or administrative proceedings initiated by the subject individual.

(b) Permit provision of personal information to contractors and vendors.

Section 2.2 of Appendix A

(a) Reduce time for retention of chain-of-custody forms showing violations.

Section 2.4 of Appendix A

(g)(13) Allow licensees to set temperature range within rule limits.

(g)(24) MRO or other designated medical person can authorize an observed collection.

(j) Flexibility on licensee internal reporting and actions when individual fails to cooperate.

Section 2.7 of Appendix A

(c) Flexibility in means of keeping specimens chilled.

(f)+(g) When licensee uses more stringent cutoff levels, tests at level set by the rule can be calculated and need not be conducted.

(h) Reduce time for laboratories to report results.

(n) Flexibility provided if lab loses certification.

(p) Flexibility to use old or new NHTSA standards for breath analysis equipment.

Section 2.8 of Appendix A

(f) Allow disposal of records of investigative findings after 3 years.

Section 2.9 of Appendix A

(d) Delete requirement for MRO determination of clinical evidence of legal drugs.

(i) Allow disposal of records of negative test results, based on scientific insufficiency, after 3 years.

Group III: Other Worthwhile Changes

A. Improvements Based on Experiences That the NRC Believes Are Needed and Proposes To Adopt

§ 26.24

(a)(5) Require return-to-duty testing after extended absences or denial of access.

(d)(1) Require onsite testers to determine validity of specimens on site.

(h) Require back calculations for BACs between 0.02 and 0.04.

§ 26.27

(b)(3)+(4) Minimum sanctions for positive test for alcohol or the use of alcohol within the protected area.

§ 26.28

• Assure that appeal rights cover all types of violations, including confirmed positive test results from applicants for unescorted access and determinations of subversion.

• Assure that relevant records are corrected if appeal is successful.

§ 26.29

(c) Assure provision of copies of records to individuals upon written request.

Section 2.4 of Appendix A

(g)(13)+(15) More restrictive temperature range for an acceptable urine specimen.

(i) Laboratory must receive specimens within 48 hours of shipment.

Section 2.7 of Appendix A

(d) Specimens questionable for adulteration or dilution at licensees' testing facilities must be shipped to HHS laboratory for testing.

(e) Require onsite testers to determine validity of specimens on site.

B. Clarifications to Existing Requirements, Changes To Reduce Interpretive Debates, and Administrative Changes Which Are Also Proposed

§ 26.2

(a) FFD program personnel to be covered by FFD rule.

§ 26.3

• To support other rule changes, revise existing definitions, create new definitions, and relocate some definitions from Section 1.2 of Appendix A.

§ 26.7

• New section ensures communications are sent to Document Control Desk.

§ 26.8

(c) Section regarding burden estimates deleted.

§ 26.20

• Minor clarifying and conforming edits (Introduction, (c), (d), (e)(2)).

(a) Offsite involvement with drugs, subversion of the testing process, and refusals to test added to policy statement.

(a) Clear and concise policy statement must be readily available.

(a) Policy must address impairment from legal drug use.

(d)(3)+(4) Policy must specify actions to be taken for subversion and refusal to provide a specimen.

(e)(1) Declaration of fitness to perform tasks assigned when contacted for call-in.

(f) Statement regarding Commission's right to review licensee policy is deleted.

§ 26.21

(a) Minor administrative and clarifying edits.

§ 26.22

(c) Supervisory training for licensee employees must be completed as soon as feasible following assignment to supervisory duty.

(c) Supervisory training for contractor employees must be completed no later than 10 days following assignment to supervisory duty.

§ 26.23

(a) Clarify that persons with a known (to the contractor or vendor) history of substance abuse must not receive assignments to the protected area without the knowledge and consent of the licensee.

§ 26.24

(a)(1) Specify that all testing prior to granting unescorted access is to be called pre-access testing.

(a)(1) Clarify that negative pre-access test result must be obtained prior to access.

(a)(2) Random testing must be conducted on weekends, backshifts, and holidays.

(a)(2) Individuals selected for random testing during an absence of 60 days or more to be tested only once to meet both random and return-to-duty testing requirements (see § 26.24 (a) (5)); tests to be reported as random.

(a)(3) Clarify conditions that initiate for-cause test.

(a)(3) Ensure removal of unfit persons and determination of fitness prior to return to duty.

(a)(4) Relocate follow-up testing requirements from § 26.27(b)(4/5) and clarify testing is to be unpredictable and tailored to medical history.

(a)(4)+(c)+(d)+(f)+(g)+(h) Minor clarifying edits.

(h) Clarify that blood testing for alcohol is for purposes of appeal.

(h) Clarify that any detectable quantity of alcohol in a blood specimen may be considered to determine FFD violation.

§ 26.25

• Clarify that EAPs must be designed to achieve early intervention and must assure confidentiality.

§ 26.27

(a)+(b) Clarifying and conforming edits.

(b)(1)+(3)+(5) Clarification of requirements with respect to access denial, removal, and return to service.

(b)(2) Conforming change regarding the threshold for alcohol policy violation.

(b)(3) People suspended must still be covered by behavioral observation, chemical testing, and sanctions for violations.

(c) Clarify that acts of subversion must be violations of policy and result in denial of unescorted access for 3 years and that the specific cause for removal must be provided in response to an inquiry.

(d) Clarify licensee handling of NRC contractors believed to be unfit.

§ 26.28

• Clarify that the appeals process must be objective and conducted by persons not associated with the FFD program.

• Clarify that an individual may submit additional relevant information

§ 26.29

(b)+(c) Clarifying and conforming edits.

§ 26.70

(a) Clarifies the records that NRC may inspect.

§ 26.71

(b)+(c) Conforming edit.

(d) Include number of subversion attempts by type in program performance reports.

§ 26.73

(a) Conforming changes.

(a) Provides additional examples of significant FFD events.

§ 26.80

(c) Conforming edit.

Section 1.1 of Appendix A

• Minor clarifying edits.

Section 1.2 of Appendix A

• Delete terms defined elsewhere in Part 26 or relocated to § 26.3.

• Add definition of limit of detection (LOD).

Section 2.1 of Appendix A

(a) Conforming editorial changes.

(b) Conforming editorial changes.

(e) Minor edit.

Section 2.2 of Appendix A

(a)+(d) Minor and conforming edits.

Section 2.3 of Appendix A

• Minor clarifying edits.

• Fitness-for-duty program personnel tested by independent personnel to the extent practicable.

Section 2.4 of Appendix A

(f) Minor clarifying changes.

(f) Current or previous specimen that fails to meet normal standards constitutes a reason to require observed testing.

(g) Minor clarifying changes.

(g)(14)+ (15)+ (18)+ (19)+ (20)+ (23)+ (24)+ (27) Conforming and clarifying changes.

(g)(23) Require secure sealing of specimen bottle.

(h)+(i) Minor clarification of sealing and labeling requirements.

(i) Continue to require specimens to be shipped to HHS laboratory or cooled within 6 hours of collection as previously required by § 2.7 (c).

(i)+(j) Conforming changes.

Section 2.5 of Appendix A

• Minor clarifying edits.

Section 2.7 of Appendix A

(b)+(d)+(f)+(g)+(h)+(i)+(k)+(l)+(m) Minor clarifying edits.

(c) Require chilling or testing within one day of arrival at HHS laboratory.

(d) MRO to report adulteration or dilution to management immediately.

(f)+(g) Standards for BAC established.

(h) Evidence of subversion must be reported by HHS laboratory.

(h) Laboratory retention of original chain-of-custody form.

(i) Specimens associated with subversion to be placed in long-term storage.

(j) Retesting of adulterated or diluted specimens need only confirm specimen not valid.

(m) HHS laboratories must have blood analysis capabilities.

(n) Specify that licensee contracts with HHS laboratories will assure that copies of records are available to licensees and NRC inspectors.

(p) Calibration standards (for calibrating equipment used to test for alcohol and screen for drugs) must be current and valid.

(p) Two-year retention period for laboratory procedure manuals after end of contract with licensee.

(p) Licensee to retain latest testing procedure manual until it is no longer performing onsite testing.

Section 2.8 of Appendix A

(a)+(b)+(c)+(e)+(f) Minor clarifying and conforming edits.

(b) Laboratory results on blind performance specimens must be evaluated and appropriate corrective actions taken.

(e) Change the proportion of blank and positive blind performance test specimens.

(e) Assure regularity of submission of blind test specimens.

(e) Adulterate or dilute and spike some blind performance specimens.

(e) Specify that initial 90-day period for blind performance testing rate applies to all new contracts with HHS laboratories.

(f) Investigation of testing process errors and inclusion of report of action taken.

(f) All false positive errors must be reported to NRC.

Section 2.9 of Appendix A

(a) Minor conforming edits.

(b)+(c)+(d)+(e)+(f) Clarifying and conforming changes to MRO duties for reporting and review of results.

(d) Clarification of clinical evidence of abuse.

(f)+(g) Medical determination of fitness to perform duties defined.

(h) Conforming language for extrapolation of BAC results between 0.02 and 0.04

(i) Minor clarifying edits.

Section 3.2 of Appendix A

- Section deleted and incorporated into § 26.29(c).

Section 4.1 of Appendix A

(a) SAMHSA replaces NIDA and change of room number.

List of Subjects in 10 CFR Part 26

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

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

PART 26—[AMENDED]

1. The authority citation for part 26 is revised to read as follows:

Authority: Secs. 53, 81, 103, 104, 107, 161, 68 Stat. 930, 935, 936, 937, 939, 948, as amended, (42 U.S.C. 2073, 2111, 2112, 2133, 2134, 2137, 2201); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

2. In § 26.2, paragraphs (a) and (d) are revised, and new paragraphs (e), and (f) are added to read as follows:

§ 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 a fitness-for-duty program which complies with this part. The provisions of the fitness-for-duty 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; and

(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;

(ii) Make removal and return-to-work recommendations or decisions;

(iii) Are involved in the selection and notification of employees for testing and in the collection and on-site testing of specimens.

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(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).

(e) For facilities in the process of being decommissioned, the scope of a fitness-for-duty program may be reduced to persons and specified areas as deemed appropriate by the NRC to protect public health and safety.

(f) Persons performing activities under this part who are covered by a program regulated by another Federal agency or State that meets the general performance objectives of this part need only be covered by those aspects of a licensee's fitness-for-duty program not included in the Federal agency or state program.

3. Section 26.3 is amended by removing the definitions for *follow-up testing, random test,* and *suitable inquiry,* revising *aliquot, confirmatory test,* and *confirmatory positive test,* and adding in alphabetical order the following definitions, *abuse of legal drugs, behavioral observation, blood alcohol concentration (BAC), HHS-certified laboratory, laboratory-confirmed positive, licensee's testing facility, medical determination of fitness, screening test, substance abuse, subversion and subvert the testing process, supervisor,* and *unconfirmed positive test result.*

§ 26.3 Definitions.

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

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 which may indicate the need to evaluate an individual's fitness for duty.

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

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

Confirmed positive test means a laboratory confirmed positive test result that has been verified as a violation of FFD policy by the Medical Review Officer (MRO) after evaluation. A ''confirmed positive test'' for alcohol is obtained as a result of a confirmation of blood alcohol levels of 0.04 percent or higher with a second breath analysis without MRO evaluation or as the result of an extrapolation back in time (back calculation) performed by the MRO.

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HHS-certified laboratory means a urine testing laboratory that maintains certification to perform drug testing under the Department of Health and Human Services (HHS) ''Mandatory Guidelines for Federal Workplace Drug Testing Programs.''

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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 the licensee or one of its vendors or contractors to perform on site the initial testing of urine specimens.

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

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Screening test means an immunoassay screen for drugs or drug metabolites to eliminate ''negative'' urine specimens from further consideration, or the first breathalyzer test for alcohol. Initial screening may be performed at the licensee's testing facility; a second screen and confirmation testing for drugs or drug metabolites must be conducted by a HHS-certified laboratory.

Substance abuse means the use, sale, or possession of illegal drugs or the abuse of legal drugs (e.g., alcohol, prescription drugs, and over-the-counter 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.

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Supervisor means any person who has the immediate oversight responsibilities to direct 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.

* * * * *

Unconfirmed positive test result means the result of a screening test for drugs and drug metabolites that indicates the presence of some drug or drug metabolite and that has the potential to be confirmed through GC/MS testing by an HHS-certified laboratory as a laboratory confirmed positive test result, or the result of a screening test for alcohol indicating a blood alcohol content of 0.02 percent or greater.

* * * * *

4. Section 26.7 is added to read as follows:

§ 26.7 Communications.

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

§ 26.8 [Amended].

5. In § 26.8, paragraph (c) is removed.

6. In § 26.20, the introductory text and paragraphs (a), (c), (d), (e), introductory text, (e)(1), (e)(2), and (f) are revised to read as follows:

§ 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 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 three 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 (e.g., alcohol, prescription and over-the-counter 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 informtion 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.

* * * * *

(c) Procedures to be utilized 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 utilized, 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 when contacted 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, 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

* * * * *

(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.

7. In § 26.21, the introductory text of paragraph (a) and paragraphs (a)(2) and (b) are revised to read as follows:

§ 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 they understand—

* * * * *

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

* * * * *

(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 three 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 licensees in the site-specific topics covered by paragraphs (a)(1), (4), and (5) of this section is completed before the granting of unescorted access to the protected area.

8. In § 26.22, the introductory text of paragraph (a) and paragraphs (a)(4) and (c) are revised to read as follows:

§ 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 they understand—

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(4) Behavioral observation techniques for detecting degradation in performance, impairment, or changes in an individual's behavior; and

* * * * *

(c) Initial training for escorts and licensee employees' supervisors must be completed before assignment of duties within the scope of this part, except that after an initial supervisory assignment, the initial training must be completed as soon as feasible but no later than 3 months following the assignment of supervisory duties. Initial training for supervisors of contractor personnel must be completed before assignment of the supervised contractor personnel to duties within the scope of this part or within 10 days after initial supervisory assignment, whichever is later. 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. The written examination must require a demonstration of adequate knowledge of the areas covered in paragraph (a) of this section. Refresher training 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 three 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 granting unescorted access to the protected area.

9. In § 26.23, the introductory text of paragraph (a) and paragraph (a)(2) are revised to read as follows:

§ 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—

* * * * *

(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 a fitness-for-duty policy will not be assigned to work within the scope of this part without the knowledge and consent of the licensee.

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10. In § 26.24, paragraphs (a), (c), (d)(1), the introductory text of (d)(2), (d)(2)(i) and (d)(2)(iv) are revised, paragraphs (e), (f), and (g) are redesignated as paragraphs (f), (g), and (h) and revised, and new paragraphs (e) and (i) are added to read as follows:

§ 26.24 Chemical 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) Preaccess testing for drugs and alcohol must be conducted within 60 days before the initial granting of unescorted access to protected areas or assignment to activities within the scope of this part unless the individual:

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

(B) Has no history of substance abuse.

(ii) Any negative drug and alcohol test meeting the standards of this part and performed within 60 days before granting unescorted access may serve as the preaccess test. A negative test result must be obtained before the granting of unescorted access unless the individual has no history indicating the use of illegal drugs or the abuse of legal drugs (e.g., alcohol, prescription, and over-the-counter drugs) and has either had a negative test result on a test meeting the standards of this part performed within six months before granting unescorted access or has been covered by a program meeting the standards of this part for two consecutive weeks during that period.

(2) Unannounced drug and alcohol tests must be imposed in a statistically random and unpredictable manner so that all persons in the population subject to testing have an approximately equal probability of being selected and tested. Random testing must include testing during all types of work periods, including weekends, backshifts, and holidays. The tests must be administered so that a person completing a test is immediately eligible for another unannounced test. At a minimum, tests must be administered on a nominal weekly frequency and at various times during the day. Reasonable efforts must be made to test persons selected for random testing. Persons off site when selected for testing, and not reasonably available for testing in a timely manner, must be tested upon returning to the site. For persons off site for more than sixty days, such tests will fulfill the requirement for return-to-duty testing and should be reported to the NRC as random tests. Random testing must be conducted at an annual rate equal to at least 50 percent of the workforce.

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

(A) Following any observed behavior or physical condition that creates a reasonable suspicion of possible substance abuse including attempts to subvert the testing process;

(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 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 pronounced fit for duty based on a medical determination of fitness. If the test is based on suspected use of alcohol and the breath analysis is negative, the individual, if determined fit for duty by a medical determination of fitness, may be returned to duty pending results of urinalysis for drugs. For-cause drug and alcohol testing must be conducted as soon as practicable, but within no more than 2 hours for an alcohol test and 8 hours for specimen collection for a drug test.

(4) Follow-up testing must be conducted on an unannounced and unpredictable basis to verify continued abstention from the use of substances as covered under this part. An individual:

(i) Whose unescorted access is reinstated after a suspension under § 26.27(b)(3); or

(ii) Is granted unescorted access after removal under § 26.27(b) (3) or (4) must be subject to follow-up testing that is tailored to the individual's medical history but not less frequently than once every month for four months and at least once every three months for the next two years and eight months after unescorted access is reinstated.

(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 indicating the use of illegal drugs or the abuse of legal drugs (e.g., alcohol, prescription and over-the-counter drugs) and either has had a negative test result on a test meeting the standards of this part performed within six months before the reinstatement of unescorted access or has been covered by a program meeting the standards of this part for two consecutive weeks during that period.

* * * * *

(c) Licensees shall test specimens collected under each type of test listed in § 26.24(a) for all substances described in paragraph 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 the Department of Health and Human Services (HHS), except that licensees may conduct tests of aliquots to determine which specimens are negative and need no further testing, provided the licensee's staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for the testing are implemented. All such testing of specimens must include tests to ensure specimen validity as required by section 2.7(e) of Appendix A to part 26. Quality control procedures for screening tests by a licensee's testing facility must include the processing of blind performance test specimens and the submission to the HHS-certified laboratory of a sampling of specimens initially analyzed as negative. Except for the purposes discussed in § 26.24(d)(2), access to the results of the above screening tests must be limited to the licensee's testing staff, the Medical Review Officer (MRO), the Fitness-for-Duty Program Manager, and employee assistance program staff, when appropriate.

(2) An individual may not be removed or temporarily suspended from unescorted access or be subjected to other administrative action based solely on an unconfirmed positive result from any drug test, other than for marijuana (THC) or cocaine, unless other evidence indicates that the individual is impaired or might otherwise pose a safety hazard. With respect to on-site screening tests for marijuana (THC) and cocaine, 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 an unconfirmed positive 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 unconfirmed positive test results from on-site 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.

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(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 Medical Review Officer 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 (e.g., positive test results and attempts to avoid detection) 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 the U.S. Department of Health and Human Services (HHS) for that purpose consistent with its standards and procedures for certification. Except for suspect specimens submitted for special processing (section 2.7(d) 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 unconfirmed positives must be subject to confirmatory testing by gas chromatography/mass spectroscopy analysis by the laboratory. Licensees shall submit blind performance test specimens to HHS-certified laboratories in accordance with the NRC Guidelines. Licensees must ensure that all collected specimens are tested and that laboratories report results for all specimens sent for testing, including blind performance test specimens.

(h) Tests for alcohol must be administered by breath analysis using breath alcohol analyses devices meeting evidential standards described in section 2.7(p)(3) of Appendix A to part 26. If the screening test shows a breath alcohol content indicating a BAC of 0.02 percent or greater, a confirmatory test for alcohol must be performed using another breath measurement instrument. A confirmatory test result showing a breath alcohol content indicating a BAC between 0.02 percent and 0.04 percent must be forwarded to the MRO for evaluation as described in section 2.9(h) of Appendix A to part 26. A confirmatory test for alcohol indicating a blood alcohol concentration (BAC) of 0.04 percent or greater must be declared a positive test. Further testing for alcohol must be administered if demanded by the individual for the purposes of obtaining additional information that could be considered during an appeal pursuant to § 26.28. Any such test must be a gas chromatography analysis of blood performed on a blood specimen drawn, with the consent of the individual, promptly after the confirmatory breath analysis. Any detectable quantity of alcohol in the blood specimen may be considered, including extrapolation back in time, to determine if a violation of the FFD policy occurred.

(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 fitness-for-duty 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.

11. Section 26.25 is revised to read as follows:

§ 26.25 Employee assistance programs (EAP).

Each licensee subject to this part shall maintain an employee assistance program to strengthen fitness-for-duty 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 employee assistance program 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).

12. Section 26.27 is revised to read as follows:

§ 26.27 Management actions and sanctions to be imposed.

(a)(1)(i) Before the initial granting of 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 a fitness-for-duty 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 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 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. To meet the suitable inquiry requirement, the identity of persons denied unescorted access or removed under the provisions of this part and the circumstances for the denial or removal, including test results, will be made available in response to a licensee's, contractor's, or vendor's inquiry supported by a release signed by the individual being investigated that authorizes the disclosure of the information. A suitable inquiry need not be conducted for any period of 30 days or less that the individual was not covered by an FFD program meeting the requirements of this part.

(5) Failure by an individual to list reasons for removal or revocation of unescorted access or failure to authorize the release of information is sufficient cause for denial of unescorted access. Temporary unescorted access pursuant to 10 CFR 73.56 may not be affected by this part provided that the applicant for unescorted access passes a chemical test conducted according to the requirements of § 26.24(a)(1).

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

(1) Personnel, including applicants, who are impaired, those whose fitness may be questionable, and those determined to have violated the licensee's fitness-for-duty policy shall be immediately denied unescorted access or otherwise removed from activities 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.

(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 off-site 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; and

(ii) A confirmatory breath test for alcohol that indicates the individual had a BAC of 0.04 percent or greater 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. Plans for treatment, follow-up, and future employment, if applicable, must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period. Although the individual must be removed from activities covered by this part, the individual must continue to be covered during any suspension period by the licensee's FFD program with respect to behavioral observation if in a work status, chemical testing, and sanctions for violations of the licensee's FFD policy. Before an individual is permitted to be returned to duty or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform such activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24(a)(5) must be conducted before the individual may be returned to duty and follow-up testing under § 26.24(a)(4) must be conducted to verify continued abstinence from the use of substances. Any subsequent violation of FFD policy, including during an assessment or treatment period, must immediately result in removal from activities described in § 26.2(a) for a minimum of 3 years from the date of removal.

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

(5) Persons removed for periods of three years or more under the provisions of paragraphs (b)(2), (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 or the abuse of legal drugs (e.g., alcohol, prescription and over-the-counter drugs) for at least three years. Before an individual is permitted to be returned or assigned to perform activities within the scope of this part, the individual must be determined to be fit to safely and competently perform these activities by an appropriate manager and a licensed physician qualified to make the medical determination of fitness. A return-to-duty test under § 26.24(a)(5) must be conducted before the individual may be assigned duties and follow-up testing under § 26.24(a)(4) must be conducted to verify continued abstinence from the use of substances. Any further violation of FFD policy must immediately result in permanent denial from activities described in § 26.2(a).

(6) Paragraphs (b) (2), (3), (4), and (5) of this section do not apply to valid prescriptions or over-the-counter drugs. Licensee sanctions for confirmed abuse of valid prescription and over-the-counter drugs must be sufficient to deter abuse of legally obtainable substances as a substitute for abuse of proscribed drugs.

(c) Any act or attempted act to subvert the testing process must be a violation of the licensee's FFD policy and must result in denial of unescorted access for a minimum of 3 years. A refusal to provide a specimen, effort to subvert the testing process, or resignation before removal for violation of company fitness-for-duty policy concerning drugs and alcohol must be recorded and

provided in response to a suitable inquiry. The specific cause for a removal, e.g., that a laboratory confirmed positive test result was obtained and that the individual resigned before an MRO review, must also be provided in response to a suitable inquiry. A record of these actions must be retained for five years following denial of any access authorization for the purpose of meeting the requirements of § 26.27(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.

13. Section 26.28 is revised to read as follows:

§ 26.28 Appeals.

Each licensee subject to this part, and each contractor or vendor implementing a fitness-for-duty 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.

14. In § 26.29, paragraph (b) is revised and paragraph (c) is added to read as follows:

§ 26.29 Protection of information.

* * * * *

(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, or 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.

15. In § 26.70, paragraph (b)(2) is revised to read as follows:

§ 26.70 Inspections.

* * * * *

(b) * * *

(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 fitness-for-duty program under the scope of the contracted activities. This includes documents, records, and reports of FFD service contractors (e.g., contracted HHS laboratory, MRO, EAP, and specimen collection services) related to licensee, contractor, or vendor FFD programs.

16. In § 26.71, paragraphs (b), (c) and (d) are revised to read as follows:

§ 26.71 Recordkeeping requirements.

* * * * *

(b) Retain relevant records pertaining to the determination of a violation of the FFD policy and the related personnel actions for a period of at least five years;

(c) Retain records of persons made ineligible for three years or longer for assignment to activities within the scope of this part under the provisions of § 26.27(b) (3), (4), and (5) or (c), until the Commission terminates each license under which the records were created; and

(d) Collect and compile fitness-for-duty program performance data on a standard form and submit these data covering the calendar year January 1st through December 31st to the Commission by March 1st of the following year. The data for each site (corporate and other support staff locations may be separately consolidated) must include: random testing rate; drugs tested for and cut-off levels, including results of tests using lower cut-off levels and tests for other drugs; workforce populations tested; numbers of tests and results by population, and type of test (i.e., pre-access, random, for-cause, etc.); substances identified; summary of management actions; number of subversion attempts by type; and a list of events reported. The data must be analyzed and appropriate actions taken to correct program weaknesses. The data and analysis must be retained for three years. Any licensee choosing to temporarily suspend individuals under the provisions of § 26.24(d) shall report test results by process stage (i.e., on-site screening, laboratory screening, confirmatory tests, and MRO determinations) and the number of temporary suspensions or other administrative actions taken against individuals based on on-site unconfirmed screening positives for marijuana (THC) and for cocaine.

17. In § 26.73, paragraph (a) is revised to read as follows:

§ 26.73 Reporting requirements.

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

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

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

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

(ii) Resulting in determinations that such an individual has violated the licensee's FFD policy;

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

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

(3) Any act that would cast doubt on the honesty and integrity of the FFD program personnel specified in § 26.2(a)(4); and

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

* * * * *

18. In § 26.80, paragraphs (a) and (c) are revised to read as follows:

§ 26.80 Audits.

(a) Each licensee subject to this part shall audit the fitness-for-duty program as needed but no less frequently than every 36 months. Licensees are responsible for determining the appropriate frequency, scope, and depth of auditing activities within the three-year period based on review of program performance indicators such as the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, previous audit findings, and ''lessons learned.'' As soon as reasonably practicable, but not later than 12 months after a significant change in fitness-for-duty personnel, procedures, or equipment, licensees shall audit the particular program element(s) affected by that change to assure continued program effectiveness. Program elements which 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 contractors and vendors 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.

* * * * *

(c) The result of the audit, along with recommendations, if any, must be documented and reported to senior corporate and site management. The resolution of the audit findings and corrective actions must be documented. The documents must be retained for three years.

Appendix A to Part 26—Guidelines for Drug and Alcohol Testing Programs

19. Section 1.1 of Appendix A to part 26 is revised to read as follows:

1.1 Applicability

(a) These guidelines apply to licensees authorized to operate nuclear power reactors and licensees who 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 such 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.

20. Section 1.2 of Appendix A to part 26 is amended by removing all definitions except *chain-of-custody, collection site,* and *collection site person,* adding the definition of *limit of detection LOD,* and revising the introductory text to read as follows:

1.2 Definitions

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

* * * * *

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

21. In section 2.1 of Appendix A to part 26, paragraphs (a), (b), and (e) are revised to read as follows:

2.1 The Substances

(a) Licensees shall, as 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 and may consider any detected drugs or metabolites when determining appropriate action during a for-cause test or analysis of any specimen suspected of being adulterated or diluted (in vivo or in vitro), substituted, or tampered with by any other means.

* * * * *

(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).

22. In section 2.2 of Appendix A to part 26, paragraphs (a), the introductory text to paragraph (d), (d)(2) and (d)(4) are revised to read as follows:

2.2 General Administration of Testing

(a) Use of a chain-of-custody 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. Chain-of-custody forms related to determinations of violations of the FFD policy must be retained for a period of at least five years following termination of the individual's unescorted access authorization as required by § 26.71(b), or the completion of all legal proceedings related to a positive test, whichever is later. Chain-of-custody forms recording specimens with negative test results and no FFD violations or anomalies may be destroyed after appropriate summary information has been recorded for program administration purposes.

* * * * *

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

* * * * *

(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 section 2.2(d)(3) of this appendix and performs collections in accordance with those instructions.

* * * * *

(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.

23. Section 2.3 of Appendix A to part 26 is revised to read as follows:

2.3 Preventing Subversion of Testing

Licensees shall carefully select and monitor persons responsible for administering the testing program (e.g., collection site persons, on-site testing facility technicians, medical review officers, 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:

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

(2) 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 five years.

(3) 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.

(4) FFD program personnel, specified in § 26.2(a), responsible for the administration of testing must be subject to drug and alcohol testing as specified in § 26.24(a). Fitness-for-duty program personnel shall be tested by personnel independent of the administration of the FFD program to the extent practicable.

24. In section 2.4 of Appendix A to part 26, paragraphs (d), (f), the introductory text of paragraph (g), (g)(4), (5), (9) through (11), (13) through (15), (18) through (20), (23) through (25), and (27), (h), (i) and (j) are revised to read as follows:

2.4 Specimen Collection Procedures.

* * * * *

(d) ''Chain-of-Custody.'' Licensee chain-of-custody 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. The signature of the person (courier) picking up the specimen being shipped to the HHS-certified laboratory does not have to be included on the chain-of-custody form as long as specimens are sealed in tamper-evident containers and there is a tracking system that identifies the courier company conveying the specimens to the laboratory, includes a shipment billing or control number, and requires the signature of the courier. Every effort must be made to minimize the number of persons handling the specimens.

* * * * *

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

(1) The individual has presented, at this or any previous collection, a urine specimen that fails to meet the standards for an acceptable specimen as provided in paragraph (g)(15) of this section, or the specimen is determined to be of questionable validity under the provisions of section 2.7 (e) of this appendix.

(2) The individual has presented a urine specimen that falls outside the normal temperature range, and the individual declines to provide a measurement of oral body temperature by sterile thermometer, as provided in paragraph (g)(15) of this section, or the oral temperature does not equal or exceed that of the specimen.

(3) The last urine specimen provided by the individual (i.e., on a previous occasion) was determined to have a specific gravity of less than 1.003 or a creatinine concentration below .2 g/L.

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

(5) 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 in the chain-of-custody 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:

* * * * *

(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.

* * * * *

(9) The collection site person shall note any unusual behavior or appearance on the chain-of-custody 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 on-site 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 that it contains a quantity of urine sufficient to meet specific licensee testing program requirements. The quantity collected must include at least 30 milliliters for the primary specimen, and a sufficient quantity for any on-site testing and testing for any additional drugs. Where collected specimens are split under the provisions of section 2.7(k) of this appendix, an additional 15 milliliters must be collected. The total to be collected should be of sufficient quantity for all analyses and reanalyses and must be predetermined by each licensee. If there is less than the required quantity of urine in the container, additional urine must be collected to reach the required quantity. Each successive void must be collected in a separate container. (The temperature of any partial specimen in its separate container must be measured in accordance with paragraph (g)(13) of this section, and the partial specimens must be inspected and sealed as described below for a full specimen. Upon obtaining the required amount, the partial specimens must be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., normally, an 8 oz. glass of water every 30 minutes, but not to exceed a maximum of 24 oz.). If the individual fails for any reason to provide a sufficient quantity of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

* * * * *

(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 determine the temperature range within which the specimen temperature must fall based on the type of temperature measuring devices used, and shall clearly specify the temperature range in its collection procedures. The temperature range of an acceptable urine specimen must be designated by the licensee and 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 is critical and must in no case exceed 4 minutes.

(14) 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 chain-of-custody form.

(15) An acceptable specimen 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 same measurements must be performed on the second specimen, and both specimens must be forwarded to the laboratory for testing.

* * * * *

(18) Alcohol breath tests must be performed by using evidential-grade equipment as specified in section 2.7(o)(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. The screening test consists of analyzing two breath specimens on the same piece of 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 breath specimen is essentially zero (less than 0.01 percent 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 breath specimen is to be collected and compared after two 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 test result is considered accurate. If the tests of the two specimens are not accurate, the series of two 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 this screening test is greater or equal to 0.02 percent BAC, a confirmatory test is to 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 purposes of obtaining additional information that could be considered during an appeal. The blood specimen should be drawn immediately, if possible. If a blood specimen cannot be drawn immediately, the procedure for calculating a BAC level from delayed collection of breath specimens and the extrapolation of BAC results (as per section 26.24(h) and described in section 2.9(i) of this appendix) must be followed for the blood specimen. 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 used. 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 section 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 sample 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.

* * * * *

(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 chain-of-custody form certifying that the specimens identified as having been collected from him or her are in fact the specimens 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 paragraph (g)(15) of this section.

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

* * * * *

(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 chain-of-custody 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 chain-of-custody 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 chain-of-custody 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 and Transportation to Laboratory or Testing Facility.'' Collection site personnel shall arrange to transfer the collected specimens to the drug testing laboratory or licensee testing facility. To minimize false negative results from specimen degradation, specimens must be sent to the HHS-certified laboratory as soon as reasonably possible but in no case should the time between specimen shipment and receipt of the specimen at the HHS-certified laboratory exceed 48 hours, or the time between shipment and screening test at the HHS-certified laboratory exceed 72 hours. Collected urine specimens must be shipped to the HHS-certified laboratory, or cooled to not more than 6 degrees centigrade (42.8°F), within 6 hours of collection. Sealed and labeled specimen bottles being transferred from the collection site to the drug testing laboratory must be placed in a second, tamper-evident shipping container which must be designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal. The collection site personnel shall ensure that the chain-of-custody documentation is attached to each urine specimen bottle.

(j) ''Failure to Cooperate.'' If the individual refuses to cooperate with the urine collection or breath analysis process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen), then the collection site person shall inform the appropriate authority and shall document the non-cooperation on the specimen chain-of-custody form. The failure to cooperate must be reported immediately to the Medical Review Officer, 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.

25. In section 2.5 of Appendix A to part 26, paragraph (a)(5) is revised to read as follows:

2.5 HHS-Certified Laboratory Personnel

(a) * * *

(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 individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the 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 section 2.7(p) of this appendix).

* * * * *

26. In section 2.6 of Appendix A to part 26, paragraph (a) is revised to read as follows:

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; maintenance of chain of custody; and proper remedial actions to be taken in response to detecting aberrant test or quality control results.

* * * * *

27. Section 2.7 of Appendix A to part 26, paragraphs (e) through (o) are redesignated (f) through (p), new paragraphs (e), (f)(3), (g)(6), and (p)(6) are added, and paragraphs (b)(1), (c), (d), (f)(1), (g) (1), (2), (3), and (5), (h) (1), (2), (3), (5), and (6), (i), (j), (k), (m)(2), (n), and (p) (1), (2), and (3)(ii) are revised to read as follows:

2.7 Laboratory and Testing Facility Analysis Procedures

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(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 chain-of-custody forms. Any direct evidence of tampering or discrepancies in the information on specimen containers and the licensee's chain-of-custody forms must be reported by the HHS-certified laboratory within 24 hours to the licensee and must be noted on the laboratory's chain-of-custody 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.

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(c) ''Short-Term Refrigerated Storage.'' Specimens that do not receive a screening test and, if appropriate, a confirmatory test within one 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 unconfirmed 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 Medical Review Officer. The Medical Review Officer shall report any adulteration or dilution evidence (excluding hydration resulting from an acceptable reason) to management immediately.

(e) ''Determining Specimen Validity.'' Specimens must be tested at a licensee's testing facility, if the licensee conducts screening tests, and at an HHS-certified laboratory to determine their validity and to detect evidence of adulteration or dilution. At a minimum, such testing must include analysis of specific gravity (SG) before being subjected to screening testing. Devices used to determine validity of the specimen must be accurate and not contaminate the specimen. A specimen acceptable for testing using the cut-off levels in paragraphs (f)(1) and (g)(2) of this section has a specific gravity greater than 1.003 and is free of detectable adulterants. Specimens determined to be of questionable validity that show evidence of dilution must be subject to both screening and confirmation testing using the limit of detection (LOD) that the laboratory is capable of performing. If the specimen's specific gravity (SG) is less than 1.001, or if there is reason to believe that the specimen has been adulterated, the laboratory need not conduct LOD testing and must report the possibly adulterated or diluted condition to the Medical Review Officer. When the MRO cannot determine if the specimen is valid or invalid, another specimen must be collected as soon as possible under the provisions of section 2.4(f) of this appendix.

(f) '' Onsite and Laboratory Screening Tests.''

(1) For the analysis of urine specimens, any screening test performed by a licensee's testing facility and the screening test performed by an HHS-certified laboratory must use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The screening test of breath for alcohol performed at the collection site must use a breath measurement device which meets the requirements of paragraph (p)(3) of this section. The following initial cut-off levels must be used when screening specimens to determine whether they are negative for the indicated substances:

SCREENING TEST CUT-OFF LEVEL
(ng/ml)

Marijuana metabolites	50.
Cocaine metabolites	300.
Opiate metabolites [1]	300.
Phencyclidine	25.
Amphetamines	1,000.
Alcohol [2]	0.04% BAC.

[1] 25 ng/ml is immunoassay specific for free morphine.

[2] 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 such cases, the results of HHS screening tests must be reported for both levels. Only the more stringent tests need be conducted, and the results for the cut-off levels above may be calculated.

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(3) Multiple screening tests (also known as rescreening) for the same drug class may be performed on:

(i) Unconfirmed positive specimens (e.g., an unconfirmed positive 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) Unconfirmed 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 a 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) All urine specimens identified as unconfirmed positive on the screening test performed by a HHS-certified laboratory must be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cut-off values listed in this paragraph for each drug, or at the cut-off values required by the licensee's unique program, where differences exist. All confirmations must be made by quantitative analysis. Concentrations which exceed the linear region of the standard curve must be documented in the laboratory record as ''greater than highest standard curve value.''

CONFIRMATORY TEST CUT-OFF LEVEL

(ng/ml)

Marijuana metabolite [1]	15.
Cocaine metabolite [2]	150.
Opiates:	
Morphine	300.
Codeine	300.
Phencyclidine	25.
Amphetamines:	
Amphetamine	500.
Methamphetamine [3]	500.
Alcohol [4]	40.04% BAC.

[1] 1Delta-9-tetrahydrocannabinol-9-carboxylic acid.

[2] Benzoylecgonine.

[3] Specimen must also contain amphetamine at a concentration ≥200 ng/ml.

[4] 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 such 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.

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(5) Confirmatory tests for opiates must include a test for 6-acetylmorphine (AM).

(6) 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 Medical Review Officer within 4 working days (6 for suspected amphetamines) after receipt of the specimen by the laboratory. Before any test result is reported, the results of screening tests, confirmatory tests, and quality control data, as applicable, must be reviewed and the test certified as an accurate report by the responsible individual at the laboratory. The report must identify the substances tested for, whether positive or negative; the cut-off(s) for each; the specimen number assigned by the licensee; any indications of tampering, adulteration, or dilution that may be present; and the drug testing laboratory specimen identification number.

(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), unconfirmed 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 Medical Review Officer may routinely obtain from the HHS-certified laboratory, and the laboratory must provide, quantitation of test results. The Medical Review Officer 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 10 CFR 26.71(d).) Quantitation of negative tests for urine specimens shall not be disclosed, except where deemed appropriate by the Medical Review Officer 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 Medical Review Officer's evaluation.

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(5) The laboratory shall retain the original chain-of-custody form and must send only to the Medical Review Officer certified true copies of the original chain-of-custody 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 section 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 fitness-for-duty program a monthly statistical summary of urinalysis and blood testing and shall not include in the summary any personal identifying information. Initial 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.

* * * * *

(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 Medical Review Officer 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 confirm that the specimen is not valid.

(k) ''Split Specimens.'' Urine specimens may be split, at the licensee's discretion, into two parts at the collection site. One half of such specimens (hereafter called the primary specimen) must be analyzed by the licensee's testing facility or the HHS-certified laboratory for the licensee's purposes as described in this appendix. The other half of the specimen (hereafter called the split specimen) may be withheld from transfer to the laboratory, sealed, and stored in a secure manner by the licensee until all processing of the primary specimen has been completed. If the primary specimen is determined to be negative and free of any evidence of subversion, the split specimen in storage may be destroyed. If the unconfirmed positive result of a screening test has been confirmed, or if the primary specimen is determined to have been subject to adulteration, dilution, or other means of testing subversion, the tested individual may request in a timely manner (as established by the licensee, but not to be restricted to less than 72 hours from the time of the individual's notification of the screening test result) that the split specimen be tested. The individual must be informed of this option. The split specimen must be forwarded on the day of the request to another HHS-certified laboratory that did not test the primary specimen. The chain-of-custody and testing procedures to which the split specimen is subject must be the same as those used to test the primary specimen and must meet the standards for retesting specimens. In other words, the quantification of the result is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite (section 2.7(j) of this appendix). The quantitative results of any second testing process shall be made available to the Medical Review Officer and to the individual tested. Except as noted in this section, all other requirements of this appendix applicable to primary specimens shall also be applicable to split specimens.

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(m) ''Laboratory Facilities.''

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(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 blood analysis for alcohol content (BAC). Any licensee testing facilities must have the capability, at the same premises, of performing 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 utilizing an HHS-certified laboratory reserves the right to inspect or audit the laboratory at any time. Licensee contracts with HHS-certified laboratories for drug testing and analyses of 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 must include review of inspection reports made under the HHS-certification program but need not duplicate areas covered by the HHS 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 a compatible drug panel and cut-off standards. The licensee shall audit the newly contracted HHS-certified laboratory within three months. The NRC reserves the right to inspect a licensee's testing facility at any time.

* * * * *

(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 of urine for drugs. Each licensee 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 three years.

(2) ''Standards and controls.'' HHS-certified laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards must be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date. All standards 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.''

* * * * *

(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) and to any applicable State statutes.

* * * * *

(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.

28. In section 2.8 of Appendix A to part 26, paragraphs (a), (b), (c), and (e) are revised, and new paragraph (f) is added to read as follows:

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 unconfirmed 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 facility's 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.

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(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 such that all the drugs for which the licensee is testing are included in approximately equal frequencies of challenge. The positive specimens must be spiked only with those drugs for which the licensee is testing. In addition, 10 percent of the positive blind specimens must be

appropriately adulterated or diluted and ''spiked'' to 60 percent of the cut-off value to challenge the laboratory's ability to determine specimen validity, as required by section 2.7 (e) of this appendix.

(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 of any errors or the unsatisfactory performance that are within their control. A record must be made and retained for a minimum of three 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 test 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 on-site 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.

29. Section 2.9 of Appendix A to part 26 is revised to read as follows:

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 Medical Review Officer before the transmission of results to licensee management officials.

(b) ''Medical Review Officer—qualifications and responsibilities.'' The Medical Review Officer 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 Medical Review Officer is to review and interpret laboratory confirmed positive 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 Medical Review Officer 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 Medical Review Officer 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 Medical Review Officer 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) ''MRO Verification of Positive Test Results.'' Before making a final decision to verify a laboratory confirmed positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result with him or her. Following verification of a laboratory confirmed positive test result as a violation of FFD policy, the Medical Review Officer shall, as provided in the licensee's policy, immediately notify the applicable employee assistance program and the licensee's management official empowered to recommend or take administrative action (or the official's designated agent). Unconfirmed test results must not be reported except as provided by § 26.24(d).

(d) ''Verification for opiates.'' Before the Medical Review Officer verifies a laboratory confirmed positive result as a violation of FFD policy and the licensee takes action for opiates, he or she shall determine that there is reasonable and substantial clinical evidence—in addition to the urine test—of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). Clinical evidence may include substantial evidence of a significant lack of reliability or trustworthiness on the part of the worker. Clinical signs of abuse include recent needle tracks or test results that are inconsistent with the ingestion of food or medication including prescription medications containing opiates (e.g., 6–AM test); clinical signs of abuse also include behavioral and psychological signs of acute opiate intoxication or withdrawal. This requirement does not apply if the GC/MS confirmation testing for opiates confirms the presence of 6-acetylmorphine.

(e) ''Reanalysis authorized.'' Should any question arise as to the accuracy or validity of a laboratory confirmed positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original specimen and such retests are authorized only at laboratories certified by HHS. The Medical Review Officer shall authorize a reanalysis of the original aliquot on timely request (as established by the licensee, but not to be restricted to less than 72 hours from the time of the individual's notification of the laboratory confirmed positive test result) of the individual tested, and shall also authorize an analysis of any split specimen stored by or for the licensee under the provisions of section 2.7(k) of this appendix.

(f) ''Results consistent with responsible substance use.'' If the Medical Review Officer 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 Medical Review Officer shall report the test result to the licensee as negative. The Medical Review Officer 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) Occasions when a medical determination of fitness, as defined in § 26.3, must be conducted include, but are not limited to, the following:

(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 paragraph (f) of this section;

(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 fitness-for-duty policy;

(iv) Before an individual being granted unescorted access when a statement from an individual obtained pursuant to § 26.27(a) shows a history of substance abuse or record of prior fitness-for-duty 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 a 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 a 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 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 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) Breath alcohol content indicating a blood alcohol concentration between 0.02 percent and 0.04 percent must be reported to the MRO for review and evaluation. The MRO shall determine whether it is appropriate to extrapolate back in time to estimate the highest BAC that the worker had while on duty with the assumption that no alcohol was consumed while on duty. In these cases, the MRO will calculate a range of possible peak BACs that could have existed while the worker was on duty and make a determination whether the result is a confirmed positive test for alcohol. A similar extrapolation process must be conducted for the results of an analysis of a blood specimen for alcohol, as provided by § 26.24(h).

(i) ''Result scientifically insufficient.'' Additionally, the Medical Review Officer, 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 Medical Review Officer may request reanalysis of the original specimen before making this decision. The Medical Review Officer 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 Medical Review Officer by making available the individual(s) responsible for day-to-day management of the licensee's test 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 three 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 such reports.

Appendix A [Amended]

30. Section 3.2 of Appendix A is removed.

31. In section 4.1 of Appendix A to part 26 is revised to read as follows:

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,'' (53 FR 11970, 11986–11989) dated April 11, 1988, 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, Substance Abuse and Mental Health Services Administration, Room 13–A–54, 5600 Fishers Lane, 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 blood specimens for alcohol, and for any other substances included in licensees' drug panels. Because the HHS-certification process does not apply to these matters, the defensibility of such tests depends on appropriate measures by licensees to assure the reported test results are valid.

(c) All contracts related to this part between licensees and their contractors and HHS-certified laboratories must require implementation of all obligations of this appendix applicable to HHS-certified laboratories.

Dated at Rockville, Maryland, this 29th day of April, 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–CE–16–AD]

RIN 2120–AA64

Airworthiness Directives; Pilatus Britten-Norman Ltd. (formerly Britten-Norman) BN–2A and BN2A MK. 111 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to supersede Airworthiness Directive (AD) 75–26–15, which currently requires repetitively inspecting the aileron mass balance clamp unit attachment for looseness on Pilatus Britten-Norman Ltd. (Pilatus Britten-Norman) BN–2A and BN2A MK. 111 series airplanes, and modifying the aileron and mass balance clamp unit if any looseness is found. The Federal Aviation Administration's policy on aging commuter-class aircraft is to eliminate or, in certain instances, reduce the number of certain repetitive short-interval inspections when improved parts or modifications are available. The proposed action would retain the repetitive inspections required by AD 75–26–15, and would require modifying the aileron and mass balance unit (at a certain time) as terminating action for the repetitive inspections. The actions specified in the proposed AD are intended to prevent failure of the aileron mass balance attachment, which could result in loss of control of the airplane.

DATES: Comments must be received on or before July 19, 1996.

ADDRESSES: Submit comments on the proposal in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–CE–16–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Pilatus Britten-Norman Limited, Bembridge, Isle of Wight, United Kingdom PO35 5PR; telephone 44–1983 872511; facsimile 44–1983 873246. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Ms. Dorenda Baker, Program Officer,