[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 26

RIN 3150 - AF12

Fitness For Duty Programs

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for Fitness for Duty (FFD) programs to update the rule and enhance consistency with advances in other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines), and other Federal drug and alcohol testing programs that impose similar requirements on NRC licensees. The proposed amendments would require nuclear power plant licensees to strengthen the effectiveness of their FFD programs in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue; and ensure consistency with the NRC's access authorization requirements for nuclear power plants. The proposed rule would ensure that individuals who are subject to these regulations are trustworthy and reliable, as demonstrated by avoiding substance abuse; are not under the influence of drugs or alcohol while performing their duties; and are not mentally or physically impaired from any other cause, that would in any way adversely affect their ability to perform their duties safely and competently.

This proposed rule would also grant, in part, a petition for rulemaking (PRM-26-1) submitted by Virginia Electric and Power Company (now Dominion Virginia Power) on December 30, 1993, by relaxing several required FFD program audit frequencies, and would partially grant a petition for rulemaking (PRM-26-2) submitted by Barry Quigley on December 28, 1999.

DATES: Submit comments on the rule by [insert date 120 days after publication in the Federal Register]. Submit comments specific to the information collections aspects of this rule by [insert date 30 days after publication in the Federal Register]. Comments received after the above dates will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after these dates.

ADDRESSES: You may submit comments on the rule by any one of the following methods. Please include the following number (RIN 3150-AF12) in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff.

Email comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking website at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; email cag@nrc.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 A.M. and 4:15 P.M. on Federal workdays.

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Copyrighted documents may be viewed at the NRC's PDR, but may not be copied. The draft Regulatory Analysis and other documents related to this rulemaking, including comments can be viewed and downloaded electronically via the NRC rulemaking web site at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/NRC/ADAMS/index.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by email to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Rebecca L. Karas, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-3711, Timothy S. McCune, Office of Nuclear Security and Incident Response, telephone (301) 415-6474, or Dr. David R. Desaulniers, Office of Nuclear Reactor Regulation,

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I. Background

A. Drug and Alcohol Testing Provisions, and General Fitness-for-Duty Program Provisions

On June 7, 1989, the Commission announced the adoption of a new rule, 10 CFR Part 26, Fitness for Duty Programs (54 FR 24468), that required each licensee authorized to operate or construct a nuclear power reactor to implement a FFD program for all personnel having unescorted access to the protected area of its plant. A subsequent final rule published in the *Federal Register* on June 3, 1993, (58 FR 31467) expanded the scope of Part 26 to include licensees authorized to possess, use, or transport formula quantities of Strategic Special Nuclear Materials (SSNM).

At the time the FFD rule was published in 1989, the Commission directed the NRC staff to continue to analyze licensee programs, assess the effectiveness of the rule, and recommend appropriate improvements or changes. The NRC staff reviewed information from several sources including inspections, periodic reports by licensees on FFD program performance, reports of significant FFD events, industry sponsored meetings and current literature, as well as initiatives by industry, the Substance Abuse and Mental Health Services Administration (SAMHSA, formerly the National Institute on Drug Abuse [NIDA]) and SAMHSA's Drug Testing Advisory Board, and recommended improvements and changes.

As a result, the NRC published proposed amendments to the FFD rule in the *Federal Register* on May 9, 1996 (61 FR 21105). The 90-day public comment period for the proposed rulemaking closed on August 7, 1996. The NRC staff reviewed and considered public comments on the proposed rule, and submitted a final rule to the Commission in a Commission paper (SECY-00-0159), dated July 26, 2000. The Commission affirmed the rule in a Staff Requirements Memorandum (SRM-M001204A) dated December 4, 2000. The affirmed rule

was sent to the Office of Management and Budget (OMB) to obtain a clearance under the Paperwork Reduction Act. The request for comments on the clearance was published in the *Federal Register* on February 2, 2001 (66 FR 8812). OMB and NRC received public comments that objected to some aspects of the rule (responses to those comments are included in Section V of this document). In SECY-01-0134, dated July 23, 2001, the NRC staff recommended withdrawing the request for clearance and preparing a new proposed rule. In a Staff Requirements Memorandum (SRM-SECY-01-0134) dated October 3, 2001, the Commission approved the staff's recommendation to withdraw the request for clearance and prepare a new proposed rule.

B. Worker Fatigue Provisions

The NRC's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors" (referred to in this document as NRC's Policy on Worker Fatigue) was first published in the *Federal Register* on February 18, 1982, (47 FR 7352), and later issued through Generic Letter (GL) 82-12, "Nuclear Power Plant Staff Working Hours," on June 15, 1982 (referred to in this document as GL 82-12). In GL 82-12, the NRC requested licensees to revise the administrative section of their technical specifications to ensure that plant administrative procedures were consistent with the revised work-hour guidelines. Those guidelines were:

(1) An individual should not be permitted to work more than 16 hours straight (excluding shift turnover time);

(2) An individual should not be permitted to work more than 16 hours in any 24-hour period, nor more than 24 hours in any 48-hour period, nor more than 72 hours in any seven day period (all excluding shift turnover time);

(3) A break of at least 8 hours should be allowed between work periods (including shift turnover time); and

(4) Except during extended shutdown periods, the use of overtime should be considered on an individual basis and not for the entire staff on a shift.

Further, the guidelines permitted deviations from these limits in very unusual circumstances if authorized by the plant manager, his deputy, or higher levels of management. The NRC's Policy on Worker Fatigue was incorporated, directly or by reference, and with variations in wording and detail, into the technical specifications of all but three nuclear power plant sites, who implemented the concept using other administrative controls.

When 10 CFR Part 26 was issued on June 7, 1989 (54 FR 24468), it focused on establishing requirements for preventing and detecting personnel impairment from drugs and alcohol. However, consistent with SRM-SECY-88-129, dated July 18, 1988, several requirements addressed other causes of impairment, including fatigue. Those requirements included general performance objectives [§26.10(a) and (b)] that provided for "...reasonable assurance that nuclear power plant personnel...are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause..." and "...early detection of persons who are not fit to perform activities within the scope of this part..." A requirement was also included in §26.20(a) for licensee policies to "...address other factors that could affect fitness for duty such as mental stress, fatigue and illness."

In a letter dated February 25, 1999, Congressmen Dingell, Klink, and Markey expressed concerns to former NRC Chairman Shirley Ann Jackson that low staffing levels and excessive overtime may present a serious safety hazard at some commercial nuclear power plants. The Union of Concerned Scientists (UCS) expressed similar concerns on March 18, 1999, in a letter from David Lochbaum to Chairman Jackson, and in the UCS report "Overtime and Staffing Problems in the Commercial Nuclear Power Industry," dated March 1999. In a letter dated May 18, 1999, to the Congressmen, the Chairman stated that the NRC staff would assess the need to revise the policy.

Soon thereafter, the Commission received a petition for rulemaking (PRM-26-2), dated September 28, 1999, from Barry Quigley. (The petition is discussed in greater detail in Section II. B.) The petition requested that the NRC amend 10 CFR Parts 26 and 55 to establish clear and enforceable work hour limits to mitigate the effects of fatigue for nuclear power plant personnel performing safety-related work.

The UCS petitioned the NRC on April 24, 2001, pursuant to 10 CFR 2.206, to issue a Demand for Information (DFI) to specified licensees. The petition asserted that Wackenhut Corporation has the contractual right to fire security guards who refuse to report for mandatory overtime, and that this contractual right conflicts with 10 CFR Part 26. The NRC denied the DFI (ADAMS Accession No. ML013230169), but addressed the concerns of the petition through the NRC's generic communication process. On May 10, 2002, the NRC issued NRC Regulatory Issue Summary (RIS) 2002-07: "Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declarations of Fitness-for-Duty." The RIS addressed the applicability of 10 CFR Part 26 to worker fatigue, the potential for sanctions related to worker FFD concerns to have adverse implications for maintaining a work environment conducive to reporting FFD concerns, and the protections afforded workers by 10 CFR 50.7, "Employee Protection."

On January 10, 2002, in SRM-SECY-01-0113, the Commission approved a rulemaking plan, Fatigue of Workers at Nuclear Power Plants, dated June 22, 2001 (referred to in this document as SECY-01-0113). In accordance with the approved plan, the NRC initiated a rulemaking to incorporate fatigue management into 10 CFR Part 26 in order to strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management worker fatigue.

During the development of proposed fatigue management requirements, the NRC observed an increase in concerns (e.g, allegations, media and public stakeholder reports)

related to the workload and fatigue of security personnel following the terrorist attacks of September 11, 2001. Following an NRC review of the control of work hours for security force personnel, and public interactions with stakeholders, the Commission issued Order EA-03-038 on April 29, 2003, requiring compensatory measures related to fitness-for-duty enhancements for security personnel at nuclear power plants, including work hour limits.

The compensatory measures imposed by Order EA-03-038 were similar to the guidelines of the NRC's Policy on Worker Fatigue. The compensatory measures differed from the Policy guidelines in a few areas in which the NRC believed it was necessary to address previously identified deficiencies in the guidelines, including the need to address cumulative fatigue from prolonged use of extended work hours, matters unique to security personnel, and stakeholder input obtained through public meetings concerning the proposed worker fatigue rulemaking and the Order. The requirements in the Order were imposed to provide the Commission with reasonable assurance that the public health and safety and common defense and security continue to be adequately protected. The provisions specified in proposed 10 CFR Part 26, Subpart I, Managing Fatigue, for security force personnel would replace the requirements imposed by Order. Differences between the proposed requirements in Subpart I and the requirements imposed by Order, and the rationale for those differences, are discussed in Section IV. D.

C. Combined Part 26 Rulemaking

On March 29, 2004, in COMSECY-04-0014, the NRC staff informed the Commission of the status of both rulemaking activities. The NRC staff also noted that because both rulemaking activities were being completed in parallel, the draft proposed fatigue rule language was based on the draft language in the proposed overall revision to Part 26, rather than on the current language in Part 26. Therefore, meaningful public comment could be confounded by

the simultaneous promulgation of two draft rules which are somewhat interdependent, and staff action to address a comment on one proposed rule could easily impact the other proposed rule, creating a high potential for the need to repropose one or both rules. In SRM-COMSECY-04-0014, dated May 25, 2004, the Commission directed the staff to combine the rulemaking related to nuclear power plant worker fatigue with the ongoing Part 26 rulemaking activity. This combined proposed rule withdraws the proposed rule published on May 9, 1996.

II. Petitions and Request for Exemption

A. Petition for Rulemaking PRM-26-1

On December 30, 1993, Virginia Electric and Power Company (now Dominion Virginia Power) submitted a Petition for Rulemaking (PRM-26-1) requesting relaxation of the required 1-year audit frequency of the FFD program and of licensee FFD programs and the program elements of contractors and vendors (C/Vs) that are relied upon by licensees. The petition requested that the first sentence of 10 CFR 26.80(a) be amended to read:

"Each licensee subject to this Part shall audit the fitness-for-duty program nominally every 24 months... In addition, audits must be conducted, nominally every 24 months, of those portions of fitness-for-duty programs implemented by contractors and vendors..."

In a letter dated March 14, 1994, the NRC informed the petitioner that the petition would be addressed in a proposed rulemaking that was under development. The NRC has periodically communicated with the petitioner regarding the status of this rulemaking since that time.

Proposed §26.41(b) would partially grant two aspects of the petition. That is, the required audit frequency for licensees and other entities who are subject to 10 CFR Part 26 would be reduced from the nominal 1-year frequency in the current rule to a nominal 2-year

frequency. Further, audits of C/V services that are performed on site and under the direct daily supervision or observation of licensee personnel would be conducted as part of the 2-year audits of the licensee or other entity's FFD program, under proposed §26.41(b).

Proposed §26.41(c)(1) would partially deny two aspects of the petition. That is, the nominal annual audit requirement for HHS-certified laboratories would be retained. In addition, the annual audit requirement would be retained for FFD program elements provided by C/Vs whose personnel "...are off site or are not under the direct daily supervision or observation of licensee personnel..."

The bases for these changes to audit requirements in the proposed rule are addressed in the subsequent sections of this supplementary information.

B. Petition for Rulemaking PRM-26-2

On September 28, 1999, Barry Quigley submitted a Petition for Rulemaking (PRM-26-2) requesting that the NRC amend 10 CFR Parts 26 and 55 to establish clear and enforceable work hour limits to mitigate the effects of fatigue for nuclear power plant personnel performing safety-related work. The PRM was published for public comment on December 1, 1999, (64 FR 67202). As described in Attachment 3 to SECY-01-0113, the petition requested the NRC to:

(1) Add enforceable working hour limits to 10 CFR Part 26;

(2) Add a criterion to 10 CFR 55.33(a)(1) to require evaluation of known sleeping disorders;

(3) Revise the NRC Enforcement Policy to include examples of working hour violations that warrant various NRC sanctions; and

(4) Revise NRC Form 396 to include self-disclosure of sleeping disorders by licensed operators.

The NRC received 176 comment letters in response to the petition. The majority of the comments (157) were in favor of a rule. These comments were principally from individuals and public interest groups. Comments received from licensees, the Nuclear Energy Institute (NEI) and Winston and Strawn, a law firm representing several utilities, were opposed to PRM-26-2. A summary of the comments and responses is available in SECY-01-0113 as Attachment 2. This document may be obtained from the NRC's website, http://www.nrc.gov, by selecting the electronic reading room and then collections of documents by type. It is also available in the NRC's Agencywide Documentation and Management System (ADAMS) under Package Accession Number ML010180224.

Although the NRC received many comments concerning the specific requirements proposed in PRM-26-2, in general, letters in support of the rulemaking —

(1) Cited the importance of ensuring that personnel who perform safety-related functions are not impaired by fatigue;

(2) Expressed concern that the NRC does not have a regulation limiting working hours and the perception that the NRC lacks the authority to enforce the guidelines in the NRC's Policy on Worker Fatigue;

(3) Asserted that the guidelines are ambiguous and that licensees interpret the guidelines as not applicable when the plant is in an outage;

(4) Asserted that "the NRC appears to look the other way" when licensee work scheduling practices appear inconsistent with the guidelines; and

(5) Expressed the concern that utility restructuring and cost competition will cause reductions in staffing levels and increased working hours and fatigue.

Further, several commenters noted that the Federal Government has established work hour limits for personnel in other industries and suggested that similar limits should apply to nuclear power plant workers.

In general, comments that opposed the petition expressed the opinion that existing regulatory requirements (i.e., technical specifications and 10 CFR Part 26) are adequate to ensure that personnel are not impaired by fatigue, that the proposed requirements would impose an unnecessary and excessive burden that could not be justified through a backfit analysis, and that industry performance data refute the petitioner's argument that a rule is necessary to prevent fatigued personnel from performing safety-related work.

The NRC has evaluated the merits of PRM-26-2, the comments received in response to the PRM, and assessed the Policy on Worker Fatigue. The NRC has concluded that the petitioner proposed a comprehensive set of requirements that could reasonably be expected to effectively address fatigue from individual and programmatic causes. However, the NRC believes that it is possible to achieve these objectives through alternative requirements that are more flexible, more directly focused on risk, and more aligned and integrated with current regulatory requirements. The proposed rule would therefore grant, in part, PRM-26-2. A detailed discussion of the principal findings that led to the decision to grant, in part, PRM-26-2 through rulemaking are included in Section IV. D. of this document. In addition, for item 3 of PRM-26-2, the NRC revised Inspection Procedure (IP) 71130.08, "Fitness For Duty Programs" on February 19, 2004, to reflect the requirements of Order EA-03-038, dated April 29, 2003, which required compensatory measures related to fitness-for-duty enhancements for security personnel at nuclear power plants, including work hour limits. The NRC plans to similarly revise the same documents during preparation of the final Part 26 rule. The self-disclosure of sleeping disorders by licensed operators (item 4) is being addressed by the NRC as a separate effort from this proposed rule through changes to Regulatory Guide 1.134, "Medical Evaluation of Licensed Personnel at Nuclear Power Plants."

C. Request for Exemption under 10 CFR 26.6

The current rule requires random drug and alcohol testing for personnel with unescorted access to the protected area of a nuclear power plant. By letter dated March 13, 1990, the International Brotherhood of Electrical Workers (IBEW) Local 1245 requested an exemption from random testing for clerical, warehouse, and maintenance workers at the Diablo Canyon Nuclear Power Plant (Diablo Canyon) under the provisions of 10 CFR 26.6. The NRC denied the request and IBEW Local 1245 sought judicial review. In 1992, the Ninth Circuit Court of Appeals affirmed the NRC's denial of the request (*IBEW, Local 1245 v. NRC*, No. 90-70647, 9th Cir., June 11, 1992). In its opinion, the court said that random testing may well be impermissible for clerical workers at Diablo Canyon who perform no safety-sensitive work and have no access to vital areas. However, in the record before the court at that time, IBEW Local 1245 had not established that such a group existed. On January 26 and December 6, 1993, IBEW Local 1245 renewed its request for exemption, specifically asking that the NRC exempt from 10 CFR Part 26 requirements for random drug testing, clerical employees at Diablo Canyon who are members of Local 1245 of the IBEW and who have unescorted access to the protected area (PA) only, but not to the radiologically controlled areas (RCAs) or vital areas (VAs) and who are not required to staff the plant's emergency response center (ERC). The PA is the area inside the security fence of a nuclear power plant, which surrounds the entire plant, and the immediately surrounding area, whereas the VAs enclose key safety systems and are located within the PA. The RCAs contain elevated levels of radiation or contamination and are generally located within the PA. The ERC is located offsite and is where the licensee evaluates and coordinates licensee activities related to an emergency, and communicates to Federal, State and local authorities responding to radiological emergencies. The NRC requested public comment on the issue in the Federal Register of May 11, 1994 (59 FR 24373). Comments were received from the nuclear industry, which largely opposed a reduction in the scope of

random testing, and from elements of the IBEW, including Local 1245, which favored it. In SRM-SECY-04-0229, dated January 10, 2005 (available on the NRC Website at http://www.nrc.gov/reading-rm/doc-collections/commission/srm/), the Commission denied the IBEW exemption request because it —

(1) Would endanger the common defense and security (as a result of increasing the likelihood of an insider threat); and

(2) Was not in the public interest (because reducing the scope of random drug testing could increase the risk to public health and safety due to a greater risk of both sabotage (insider threat due to vulnerability to coercion) and of an accident (impaired worker)).

Consequently, this proposed rule would maintain the current requirement for random drug and alcohol testing for personnel with unescorted access to the PA at a nuclear power plant.

III. Abbreviations

The following abbreviations and acronyms are used in this Statement of Considerations.

AEA	Atomic Energy Act
ASDs	Alcohol screening devices
BAC	Blood alcohol concentration
CPL	Conforming products list
C/V	Contractor/vendor
DOT	Department of Transportation
EAP	Employee assistance program
EBT	Evidential breath testing device
EPRI	Electric Power Research Institute

FFD	Fitness for duty
GC/MS	Gas chromatography/mass spectrometry
HHS	Department of Health and Human Services
IBEW	International Brotherhood of Electrical Workers
KAs	Knowledge and abilities
LOD	Limit of detection
LOQ	Limit of quantitation
mg/dL	Milligrams per deciliter
MRO	Medical Review Officer
NEI	Nuclear Energy Institute
ng/dL	Nanograms per deciliter
NHTSA	National Highway Transportation Safety Administration
NRC	Nuclear Regulatory Commission
NSF	National Sleep Foundation
OMB	Office of Management and Budget
PDFFDI	Potentially disqualifying fitness-for-duty information
pH	potential of hydrogen
POGO	Project on Government Oversight
PROS	Professional Reactor Operator Society
QA/QC	Quality assurance/quality control
SAE	Substance Abuse Expert
SAMHSA	Substance Abuse and Mental Health Services Administration
SSNM	Strategic special nuclear material
THC	Tetrahydrocannabinol, delta-9-tetrahydrocannabinol-9-carboxylic acid

UCS Union of Concerned Scientists

6-AM 6-acetylmorphine

IV. Discussion of Proposed Action

A. Discussion Overview

A review of FFD program experience confirms that the regulatory approach of 10 CFR Part 26 is fundamentally sound and continues to provide a means of deterrence and detection of substance abuse at licensee facilities. NRC Information Notice 2003-04, "Summary of Fitness-for-Duty Program Performance Reports," dated February 6, 2003, provides the latest published summary of program performance. This document may be obtained from the NRC's website, http://www.nrc.gov, by selecting the electronic reading room and then collections of documents by type. It is also available in ADAMS under Accession No. ML030350473.

Nonetheless, the NRC believes that revisions are needed to improve the effectiveness and efficiency of FFD programs; enhance consistency with advances in similar rules and guidelines, including the HHS Guidelines and other Federal drug and alcohol testing programs that place similar requirements on the private sector; strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue; enhance consistency with the NRC's access authorization requirements; improve clarity in the organization and language of the rule; and improve Part 26 by eliminating or modifying unnecessary requirements.

B. Discussion of Goals of the Rulemaking Activity

The Nuclear Regulatory Commission (NRC) proposes to amend 10 CFR Part 26, Fitness For Duty Programs. The proposed goals are to:

(1) Update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs and other Federal drug and alcohol testing programs (e.g., those required by the U.S. Department of Transportation [DOT]) that impose similar requirements on the private sector.

(2) Strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management worker fatigue;

(3) Improve the effectiveness and efficiency of FFD programs.

(4) Improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

(5) Improve Part 26 by eliminating or modifying unnecessary requirements.

(6) Improve clarity in the organization and language of the rule.

(7) Protect the privacy and due process rights of individuals who are subject to Part 26.

Each of these goals is expected to result in substantial improvements in FFD programs. Many changes in the proposed rule relate to each goal. The major changes for each subpart, and the reasons for those changes, are described in Section IV. C and D of this document. For each of the many specific changes that are being proposed, detailed discussions are included in Section VI. However, the following discussion provides a description of each goal, a basis for

the need to accomplish that goal, and several examples of proposed changes to the rule that would contribute to meeting the goal.

Goal 1 – Update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (referred to in this document as the HHS Guidelines) and other Federal drug and alcohol testing programs (e.g., those required by the U.S. Department of Transportation [DOT]) that impose similar requirements on the private sector. Goal 1 is central to this rulemaking activity. Many changes are included in the proposed rule to maintain consistency with advances in the conduct of FFD programs, including changes in the HHS Guidelines. The 1994, 1998, and 2004 revisions to the HHS Guidelines differ substantially from the 1988 version of the Guidelines, upon which the current rule is based.

The President of the United States designated HHS as the agency responsible for the Federal workplace drug testing program, and HHS' Substance Abuse and Mental Health Services Administration (SAMHSA) is responsible for maintaining the HHS drug testing guidelines based on the most recent research and the accumulation of lessons learned from the Federal drug testing program, as well as others who are regulated. The NRC has historically relied on HHS to establish the technical requirements for urine specimen collection, testing and evaluation, and has only deviated from HHS' guidelines for considerations that are specific to the nuclear industry. Updating Part 26 to be consistent with HHS' most recent Guidelines ensures that NRC regulations continue to be scientifically and technically sound.

Further, the HHS-certified laboratories that Part 26 requires licensees to use for drug testing are required by HHS to follow the HHS Guidelines in order to retain their certification. Basing Part 26 on older versions of the HHS Guidelines, or deviating from those Guidelines, increases the cost of drug testing for the nuclear industry. Therefore, updating Part 26 to

increase consistency with the HHS Guidelines not only ensures that Part 26 is based on the best scientific and technical information available, but also avoids imposing an unnecessary and costly regulatory burden on the nuclear industry.

One example of an improvement from enhancing consistency with the HHS Guidelines is that several cutoff levels for detection of various drugs would be updated, including a revised lower cutoff level for the marijuana metabolite, THC. The lower cutoff level will provide greater assurance that individuals who use marijuana are identified.

Additionally, a revision to the HHS Guidelines, published in the Federal Register on April 13, 2004 (69 FR 19643) as a final rule, includes requirements for instrumented specimen validity tests to determine whether a urine specimen has been adulterated, diluted, or substituted. This proposed rule would adopt significant portions of the final HHS specimen validity testing provisions. The new validity testing requirements will substantially improve the effectiveness of the measures to guard against subversion of the testing process that are contained in current Part 26.

Several other provisions for drug testing are under consideration by HHS and were published as a proposed rule for public comment in the Federal Register on April 13, 2004 (69 FR 19672). One proposed change to 10 CFR Part 26 that was included from the proposed HHS Guidelines is permission for licensees to use non-instrumented validity testing devices to determine whether a urine specimen must be subject to further testing at an HHS-certified laboratory because it may have been adulterated, diluted, or substituted, in lieu of the instrumented validity testing required in the April 13, 2004, final version of the HHS Guidelines. Although the HHS Guidelines that would permit Federal drug testing programs to use non-instrumented validity testing devices for initial testing of urine specimens are not yet final, some NRC licensees desired the flexibility to use these testing methods. A technical basis for use of those methods is included in Section VI. However, the NRC is not proposing to include other

provisions in the proposed HHS Guidelines at this time. Those provisions include permitting the drug testing of specimens other than urine (e.g., hair, saliva, sweat), requirements for split specimen procedures for all specimens, and HHS certification of instrumented initial test facilities, which would be analogous to licensee testing facilities. Should such provisions be included in final HHS Guidelines in the future, the NRC will consider incorporating them into 10 CFR Part 26 at that time.

In addition to the proposed changes to 10 CFR Part 26 that incorporate the recent revisions to the HHS Guidelines, the Department of Transportation (DOT) revised its Procedures for Transportation Workplace Drug and Alcohol Testing Programs [49 CFR 40, 65 FR 41944; August 9, 2001] to include the use of oral fluids (i.e., saliva) as acceptable specimens for initial alcohol screening tests. The proposed rule would also reflect the new oral fluids testing technology to provide FFD programs with increased flexibility in administering initial alcohol tests.

Because the HHS Guidelines do not establish requirements for alcohol testing, NRC relies on the DOT regulations, in part, to ensure that the alcohol testing provisions of Part 26 remain scientifically sound and legally defensible. Because the DOT programs test a much larger number of individuals, in comparison to the number of alcohol tests that are conducted under Part 26, basing the NRC's alcohol testing regulations on portions of the DOT regulations reflects the lessons learned from that larger population.

Goal 2 – Strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue. This goal is central to this rulemaking activity. Proposed Subpart I, Managing Fatigue, would add clear and enforceable requirements for licensee management of worker fatigue to 10 CFR Part 26. The proposed requirements would reduce the potential for

worker fatigue, and therefore strengthen the effectiveness of FFD programs at nuclear power plants and substantially increase the protection of public health and safety and the common defense and security. Section VI discusses the specific reasons for each proposed worker fatigue provision. Section IV. D provides a detailed discussion of the overall basis for establishing fatigue management requirements for FFD programs, and the benefits expected to result.

Goal 3 – Improve the effectiveness and efficiency of FFD programs. The NRC has gained experience in the actual implementation of FFD programs since Part 26 was originally promulgated. The NRC is proposing many changes throughout Part 26 based on that experience in order to improve the industry's programs specifically to increase both the effectiveness of the programs in achieving the goals of Part 26, and the efficiency of program operations. Increasing the effectiveness and efficiency of FFD programs will enhance the protection of public health and safety and the common defense and security.

One example of a change related to Goal 3 is the proposed reduction in the period within which pre-access testing must be performed from 60 days, in current §26.24(a)(1), to 30 days or less, in proposed Subpart C [Granting and Maintaining Authorization]. This proposed change would improve the effectiveness of the pre-access test in detecting drug and alcohol use by individuals who are applying for authorization to perform the types of job duties that require them to be subject to Part 26 (see proposed §26.25 [Individuals subject to the fitness-for-duty program]). Reducing the number of breath specimens required for alcohol testing from two each for initial and confirmatory testing, in current Section 2.4(g)(18) in Appendix A to Part 26, to one specimen for the initial test and one for the confirmatory test, if required, in proposed §26.91(d), would increase the efficiency of FFD programs without compromising the accuracy and validity of alcohol test results.

Another example would be establishing a regulatory framework for the management of worker fatigue that appropriately balances the need for flexibility to manage plant exigencies and worker individual differences relative to fatigue with the need for more readily enforceable requirements and efficient NRC oversight of licensee compliance with the requirements and performance objectives of the rule.

Goal 4 – Improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. Current FFD and access authorization requirements each contain provisions that relate to establishing the trustworthiness and reliability of personnel prior to granting unescorted access to the protected areas of nuclear power plants. The NRC has determined that, because both sets of requirements share this same goal, revising Part 26 would clarify the relationship between these requirements, particularly for licensee access authorization decisions regarding personnel who move between sites with some interruption in their status of having unescorted access to a nuclear power plant. In addition, some requirements in Part 26 address the granting of temporary unescorted access. In response to the terrorist attacks of September 11, 2001, on the World Trade Center and the Pentagon, and the current threat environment, the Commission took action to curtail the use of temporary unescorted access at commercial nuclear power plants. Temporary unescorted access was eliminated by orders issued January 7, 2003, which imposed compensatory measures on existing access authorization programs. Therefore, it is necessary to revise the related provisions in Part 26.

Goal 5 – Improve 10 CFR Part 26 by eliminating or modifying unnecessary requirements. The proposed rule would incorporate a number of changes to eliminate or modify unnecessary requirements. The experience NRC has gained over the years since Part 26 was promulgated have enhanced the agency's understanding of implementation by the

industry, and the NRC now proposes to eliminate or modify some provisions, while at the same time maintaining the protection of public health and safety and the common defense and security.

For example, because of inconsistencies in FFD and access authorization requirements for conducting employment inquiries, many licensees contacted an individual's previous employers twice — once to obtain the information required under Part 26 and once to obtain the information required for access authorization. Proposed revisions to Part 26 would clarify that licensees may obtain information to satisfy FFD suitable inquiry requirements and related access authorization requirements at the same time when conducting an employment inquiry.

Goal 6 – Improve clarity in the organization and language of the rule. The proposed rule is organized to facilitate implementation, as compared to the current rule which has generated many questions from licensees. Therefore, in the proposed rule, the NRC has substantially reorganized the requirements to eliminate redundancies, to group related requirements, and to present requirements in the order in which they would apply to licensees' FFD processes. In addition, the NRC has proposed many language changes to improve clarity. The NRC has undertaken this substantial reorganization to improve the protection of public health and safety and the common defense and security by substantially reducing the likelihood of variations in FFD programs across the industry through differing interpretations of the rule. The proposed rule is clearer in both organization and language, and is expected to result in more uniform implementation, and, consequently, more consistency in achieving the Part 26 goals.

In contrast to certain NRC regulations, Part 26 includes a considerable number of detailed requirements. In the public meetings held during the development of this proposed rule, industry representatives indicated that they consider this level of detail necessary to help protect individual privacy and ensure consistency in implementing the requirements. Additionally, industry representatives indicated that this high level of detail can help to avoid

unnecessary litigation between licensees and individual personnel regarding worker non-compliance with specific drug and alcohol testing performance steps. Such litigation would be more likely if those specific performance steps were not required by NRC rule. The level of detail and the enhanced clarity in the new language and organization included in proposed Part 26 have eliminated the need for a guidance document. In the public meetings described in Section V, industry representatives commented that a guidance document would not have the same weight as a rule, and that both licensees and individuals should be protected fully with rigor and specificity in a rule. Industry therefore desired the rule to be more specific and detailed, in lieu of a guidance document.

Goal 7 – Protect the privacy and due process rights of individuals who are subject to 10 CFR Part 26. This goal is an implicit objective of the current rule, and the proposed rule would also continue to protect the privacy and due process rights of individuals who are subject to 10 CFR Part 26. The NRC, DOT, and HHS have all gained experience in implementing workplace drug and alcohol testing programs. This experience has led DOT and HHS to modify many of their requirements for such testing to more clearly protect privacy and due process rights of individuals. Many of the proposed changes to Part 26 related to this goal are based on either DOT or HHS requirements. The NRC believes the protection of individual rights to be of the highest importance, and proposes changes to Part 26 to ensure that those rights are protected through rule language developed using the best available information. One example of such a change is that “Bottle B”, the second portion of a split urine specimen, would now only be tested with the donor’s written permission.

C. Overview of Proposed Rule

The proposed rule would be divided into subparts that contain related requirements. This proposed change would be made to improve the ease of implementing the rule by

grouping related requirements and presenting them generally in the order in which they would apply to licensees' and other entities' FFD processes. Each subpart would be assigned a descriptive title to aid users in locating rule provisions and to simplify cross-referencing within the proposed rule. The major topics addressed in each subpart and the reasons that the major changes are being proposed are described below. A detailed cross-reference table between the current and proposed Part 26 provisions is included at the end of this notice.

Subpart A Administrative Provisions

The first subpart, proposed Subpart A [Administrative Provisions], would replace the General Provisions portion of the current rule, but continue to address the same subject matter. Thus, Subpart A would address the purpose and scope of the rule, provide definitions of important terms used in the proposed rule, and update current provisions related to requests for specific exemptions, interpretations of the rule, and communications with the NRC.

Subpart B Program Elements

Subpart B [Program Elements] of the proposed rule would reorganize and amend current §§26.10–26.29, which specify the performance objectives that FFD programs would be required to meet and the FFD program elements that licensees and other entities must implement to meet the performance objectives. However, the proposed rule would not include current §26.27 [Management actions and sanctions to be imposed] in Subpart B for two reasons. First, at the public meetings described in Section V. B, stakeholders requested that the rule be reorganized to be consistent with the order in which licensees and other entities would implement their programs. Because Subpart B would be focused on establishing the framework of FFD programs, it would be premature to present requirements related to implementing the FFD program (i.e., imposing sanctions on an individual for violating the FFD

policy) at this point in the proposed rule. Second, the stakeholders suggested, and the NRC staff concurred after consideration, that the subject matter of current §26.27 is sufficiently important and complex that a separate subpart is warranted. Therefore, the proposed rule would present requirements related to management actions and sanctions in proposed Subpart D [Management Actions and Sanctions to be Imposed].

Subpart C Granting and Maintaining Authorization

Subpart C [Granting and Maintaining Authorization] of the proposed rule would substantially amend current FFD requirements related to the process that licensees and other entities must follow in determining whether an individual is trustworthy and reliable, as demonstrated by avoiding substance abuse, and can be expected to perform his or her job duties safely and competently. The proposed rule would introduce the concept of "authorization" to Part 26 to refer to the status of an individual who the licensee or other entity has determined can be trusted to perform the job duties described in proposed §26.25 [Individuals subject to the fitness-for-duty program], as a result of the process described in this subpart. For example, in the case of nuclear power plant personnel, an individual who is "authorized" under Part 26 may be permitted to have unescorted access to protected areas in nuclear power plants if the individual's job requires such access.

The NRC has published other requirements, such as 10 CFR 73.56, that establish additional steps that licensees and other entities must take as part of the process of determining whether to grant authorization to an individual or permit an individual to maintain authorization. These additional requirements focus on aspects of an individual's character and reputation other than substance abuse, and, among other steps, require the licensee or other entities who are subject to the rule to conduct a psychological assessment of the individual, a credit and criminal history check, and interview individuals who have knowledge of the applicant

for authorization. However, as discussed in Section IV. B, historically there have been some inconsistencies and redundancies between the Part 26 requirements related to granting and maintaining authorization and the other, related regulations, particularly the NRC's access authorization requirements for nuclear power plant personnel. The inconsistencies have led to many implementation questions from licensees, as well as inconsistencies in how licensees have implemented the requirements. The redundancies have, in other cases, imposed an unnecessary burden on licensees. Therefore, a central goal of adding Subpart C to the proposed rule is to eliminate those inconsistencies and redundancies to ensure that licensees and the other entities who are subject to the rule have clear and easily interpretable requirements to follow when determining whether to grant or maintain an individual's authorization under Part 26 and also under other, related requirements, including, but not limited to, the access authorization orders issued by the NRC to nuclear power plant licensees on January 7, 2003.

The requirements in proposed Subpart C are based upon several fundamental changes to the NRC's approach to the authorization requirements in current Part 26. The primary concern, which Subpart C is designed to address, is the necessity of increasing the rigor of the authorization process to provide high assurance that any individual who is granted and maintains authorization is trustworthy and reliable, as demonstrated by avoiding substance abuse. The necessity for increased rigor in the authorization process is discussed in Section IV. C with respect to proposed §26.23(a) in terms of the increased insider threat since the terrorist attacks of September 11, 2001. One change to current Part 26 authorization requirements that reflects this concern is the elimination of temporary access authorization requirements in the second sentence of current §26.27(a)(4). Other changes are discussed in Section IV with respect to the specific provisions that would incorporate them.

A second, related change to the NRC's approach to authorization requirements, which has informed proposed Subpart C, is an increased concern with the sharing of information about individuals between licensees and other entities. At the time the current Part 26 was developed, the industry structure was different and personnel transfers between licensees (i.e., leaving the employment of one licensee to work for another licensee) with interruptions in authorization were less common. Most licensees operated plants at a single site and maintained an FFD program that applied only to that site. When an individual left employment at one site and began working for another licensee, the individual was subject to a different FFD program that often had different requirements. Because some licensees were reluctant to share information about previous employees with the new employer, licensees often did not have access to the information the previous licensee had gathered about the individual and so were required to gather the necessary information again. The additional effort to collect information that another licensee held created an unnecessary burden on both licensees. But, because few individuals transferred, the burden was not excessive.

However, since 1989, the industry has undergone significant consolidation and developed new business practices to use its workforce more efficiently. Industry efforts to better use expertise and staffing resources have resulted in the development of a large transient workforce within the nuclear industry that travels from site to site as needed, such as roving outage crews. Although the industry has always relied upon C/Vs for special expertise and staff for outages, the number of transient personnel who work solely in the nuclear industry has increased and the length of time they are on site has decreased. Because the current FFD regulations were written on the basis that individual licensees would maintain independent, site-specific FFD programs and would share limited information, and that the majority of nuclear personnel would remain at one site for years, the regulations do not adequately address the transfer of personnel between sites.

These changes in the industry have increased the need for information sharing among licensees and C/Vs. The increased insider threat since September 11, 2001, has also heightened the need for information sharing among licensees and C/Vs to ensure that licensees and other entities have information that is as complete as possible about an individual when making an authorization decision. To address this need, the access authorization orders issued by the NRC to nuclear power plant licensees on January 7, 2003, mandated increased sharing of information. In addition, proposed Subpart C would require licensees and other entities to collect and share greater amounts of information than under the current rule, subject to the protections of individuals' privacy that would be specified in proposed §26.37 [Protection of information]. As a result, individuals who are subject to the rule would establish a detailed "track record" within the industry that would follow them if they change jobs and move to a new position that requires them to be granted authorization by another licensee or entity who is subject to the rule. This increased information sharing would contribute to providing high assurance that individuals who are granted and maintain authorization are trustworthy and reliable when individuals move between FFD programs.

However, a consequence of increased information sharing is that one violation of any licensee's FFD policy has greater potential to end an individual's career. Although an individual who has an active substance abuse problem cannot be permitted to hold authorization, the NRC continues to affirm that individuals who pursue treatment, stop abusing drugs or alcohol, and maintain sobriety for an extended period of time should regain the public's trust. The length of time that an individual must maintain sobriety in order to demonstrate that he or she can again be trusted with the public's health and safety and the common defense and security has been a matter of debate since Part 26 was originally under development. However, the research literature continues to indicate that individuals who maintain sobriety past the first 3 years following treatment have substantially reduced recidivism rates (i.e., relapsing into

substance abuse) than during the first 3 years after treatment and there is a further drop in recidivism rates after 5 years of sobriety.

Despite these research findings, some individuals who have had one confirmed positive test result have been prevented from working in operating nuclear power plants. The increased information sharing that would be required under Subpart C has the potential to result in a greater number of such individuals being banned from working in the industry. Therefore, several requirements would be added to proposed Subpart C to minimize such consequences for individuals who are able to demonstrate that they have resolved a substance abuse problem. Additional requirements for protecting information that would be gathered about individuals under proposed Part 26 would be specified in proposed §26.37 [Protection of information]. The detailed changes to current requirements are discussed in Section VI with respect to the specific provisions that would incorporate them.

In general, the authorization requirements in proposed Subpart C would be structured according to whether an individual who has applied for authorization has previously held authorization under Part 26. If an individual has not established a “track record” in the industry, the proposed rule would require licensees and other entities to meet an extensive set of requirements before granting authorization to the individual. If an individual has established a favorable track record in the industry, the amount of original information gathering that the proposed rule would require licensees and other entities to complete before granting authorization to the individual would be reduced. The need for original information gathering in these instances would be reduced because, under the proposed rule, licensees and other entities would have access to all of the information that previous FFD programs had collected about the individual.

For individuals who have established a favorable track record in the industry, the steps that licensees and other entities would be required to complete in order to grant authorization to

an individual would also depend upon the length of time that has elapsed since the individual's last period of authorization was terminated and the amount of supervision to which the individual was subject during the interruption. (The term, "interruption," refers to the interval of time between periods during which an individual holds authorization under Part 26.) In general, the more time that has elapsed since an individual's last period of authorization ended, the more steps that the proposed rule would require licensees and other entities to complete before granting authorization to the individual. However, if the individual was subject to behavioral observation under a Part 26 program or continued to be subject to random drug and alcohol testing during the interruption, the proposed rule would require licensees and other entities to complete fewer steps in order to grant authorization to the individual. There are several reasons that the proposed rule would require fewer steps in the authorization process for these individuals.

First, individuals who have established a favorable work history in the industry have demonstrated their trustworthiness and reliability from previous periods of authorization, so they pose less potential risk to public health and safety and the common defense and security than individuals who are new to the industry. Much is known about these individuals. Not only were they subject to the initial background screening requirements before they were initially granted authorization, but, while they were working under a Part 26 program, they were watched carefully through on-going behavioral observation, repeatedly attained negative results from random drug and alcohol tests, and demonstrated the ability to consistently comply with the many procedural requirements that are necessary to perform work safely at operating power reactor facilities.

Second, individuals who have established a favorable work history in the industry and whose authorization has been interrupted for only a short period would be unlikely to develop an active substance abuse problem during the interruption. The shorter the period of time since

the individual's last period of authorization ended, the less likely it is that the individual would have developed an active substance abuse problem or undergone significant changes in lifestyle or character that would diminish his or her trustworthiness, reliability, and ability to perform work safely and competently.

Further, if the individual was also subject to supervision under some elements of a Part 26 program (e.g., behavioral observation, a requirement to report any arrests, random drug and alcohol testing) during the period that his or her authorization was interrupted, the higher the assurance that the individual does not have an active substance problem. And, the less likely it would be that the individual could have undergone significant changes in lifestyle or character that would be undetected.

Therefore, the proposed rule would establish categories of requirements for granting authorization to an individual that would vary, based upon whether the individual has previously held authorization under Part 26; whether the individual's last period of authorization was terminated favorably or unfavorably; how long it has been since the individual last held authorization under Part 26; and whether the individual was subject to any elements of a Part 26 program during the interruption period. Proposed §26.55 [Initial authorization] would establish authorization requirements for individuals who have not previously held authorization under Part 26 and individuals who have not held authorization within the past 3 years. Proposed §26.57 [Authorization update] would establish authorization requirements for individuals who previously held authorization under Part 26, whose last period of authorization was terminated favorably more than 1 year ago but less than 3 years ago. Proposed §26.59 [Authorization reinstatement] would establish authorization requirements for individuals who previously held authorization under Part 26 and whose last period of authorization was terminated favorably within the past year. Proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information] would define the steps that licensees and other

entities must take in granting authorization to an individual about whom potentially disqualifying FFD information has been disclosed or discovered.

The time periods used to establish these categories of authorization requirements would be consistent with the categories established in the access authorization orders issued by the NRC to nuclear power plant licensees on January 7, 2003. Basing the proposed requirements on elapsed time is consistent with the programs of other Federal agencies who have similar needs to control access to sensitive information and protected areas. In addition, these time periods have been used successfully within nuclear power plant access authorization programs since 1989 and have met the NRC's goal of ensuring that individuals who are granted unescorted access are trustworthy and reliable. Therefore, the proposed rule would incorporate these time periods within Part 26.

In general, the steps that would be required to grant authorization to an individual who has recently held authorization and whose most recent period of authorization was terminated favorably would be less extensive than the steps required for applicants for authorization who are new to the industry or those who have not recently held authorization. In addition, the requirements for a rigorous evaluation process contained in the current §26.27(e) would be strengthened and licensees and other entities would be required to meet them before granting authorization to an individual about whom potentially disqualifying FFD information has been disclosed or discovered (see proposed §26.69). The proposed rule would require licensees and other entities to obtain and review a written self-disclosure from the applicant and an employment history, and ensure that a suitable inquiry and pre-access drug and alcohol testing are completed before granting authorization to an individual, with certain exceptions. The proposed exceptions to the self-disclosure and employment history, suitable inquiry, and pre-access testing requirements would be specified in proposed §§26.61 [Self-disclosure and employment history], 26.63 [Suitable inquiry], and 26.65 [Pre-access drug and alcohol testing],

respectively. The proposed rule would also require licensees and other entities to ensure that applicants are subject to random testing, as specified in proposed §26.67 [Random drug and alcohol testing of individuals who have applied for authorization].

Subpart D Management Actions and Sanctions

Subpart D [Management Actions and Sanctions] of the proposed rule would replace current §26.27(b) and (c) and divide the current provisions into two separate sections that specify requirements for responding to FFD policy violations in proposed §26.75 [Sanctions], and indications of impairment in proposed §26.77 [Management actions regarding possible impairment]. The current rule would be reorganized in response to stakeholder requests that were made during the public meetings discussed in Section V. The stakeholders requested that the proposed rule generally reflect the order in which the requirements apply to licensees' and other entities' FFD processes and that related requirements be grouped into separate sections. Therefore, this change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

In general, proposed Subpart D would include three significant changes from the related provisions in the current rule that are each intended to provide a stronger deterrent to engaging in the unwanted actions specified in the proposed subpart. First, the proposed rule would increase the severity of the minimum sanctions that are required if an individual violates a licensee's or other entity's FFD policy. The more stringent sanctions would be necessary in order to strengthen the effectiveness of the rule in providing high assurance that individuals who are subject to this part are trustworthy and reliable, as demonstrated by avoiding substance abuse, and by increasing the assurance that only individuals who are fit for duty are permitted to perform the job duties listed in proposed §26.25 [Individuals subject to the fitness-for-duty program].

Second, the proposed rule would require licensees and other entities who are subject to the rule to impose the same sanctions for an FFD violation involving the abuse of alcohol as required for the abuse of illegal drugs. Impairment caused by alcohol abuse creates a risk to public health and safety that is fundamentally similar to the risk posed by the use of illegal drugs. Some licensees, however, have imposed lesser sanctions for alcohol violations, an approach that is inconsistent with the NRC's intent. Therefore, the proposed rule would rectify this situation by explicitly requiring the same minimum sanctions for abuse of alcohol as currently required for the use of illegal drugs.

Third, the proposed rule would add the sanction of permanent denial of authorization for any individuals who subvert or attempt to subvert the testing process. The current rule permits licensees and other entities to have flexibility in establishing sanctions for actions such as refusing to submit to testing and attempting to subvert the testing process by submitting an adulterated or substitute specimen. As a result, different FFD programs have imposed different sanctions and some individuals have been granted authorization or permitted to maintain authorization when they have committed such acts. However, acts to defeat the testing process indicate that an individual is not trustworthy and reliable and suggest that the individual may be engaging in substance abuse that could pose a risk to public health and safety and the common defense and security. Therefore, the proposed rule would establish a minimum sanction that all FFD programs must impose to deter attempts to subvert the testing process as well as provide high assurance that individuals who are granted and maintain authorization can be trusted to comply with the rules and regulations to which they are subject.

These three changes would be made to meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs, as discussed in Section IV. B. Other changes to current §26.27(b) and (c) in proposed Subpart D would be made primarily to eliminate or modify unnecessary requirements and clarify the intent of current provisions.

Subpart E Collecting Specimens for Testing

Subpart E [Collecting specimens for testing] of the proposed rule would reorganize and amend the requirements related to collecting specimens for drug and alcohol testing that are contained in current §26.24 [Chemical and alcohol testing] and interspersed throughout current Appendix A to Part 26. The proposed subpart would group the related requirements and present them in the order in which they would be implemented by FFD programs. The proposed rule would also eliminate some redundancies in the provisions of the current rule that are related to specimen collections, as is discussed in Section VI, with respect to the specific provisions. These proposed changes would be made to meet Goal 6 of the rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B.

In general, the procedures in this subpart would be more detailed than those in Appendix A to the current rule, and also those NRC regulations that are based upon a risk-informed, performance-based approach, for several reasons. First, the more detailed procedures in proposed Subpart E would increase the consistency of Part 26 drug and alcohol specimen collection procedures with those of other Federal agencies and therefore would take advantage of the scientific and technical advances that have been made in workplace drug and alcohol testing programs since the current Part 26 was promulgated, as discussed in Section IV. B. Second, the proposed rule would permit Part 26 FFD programs to accept and rely upon other Part 26 programs, as well as the programs of other Federal and State agencies, to a much greater extent than is permitted under the current rule. The proposed permission to rely on other programs would improve the effectiveness and efficiency of FFD programs (Goal 3 of the rulemaking) and improve 10 CFR Part 26 by eliminating or modifying unnecessary requirements (Goal 5 of the rulemaking). For example, under proposed §26.69(b)(6), the proposed rule would permit licensees and other entities to rely upon another Part 26 program's drug and alcohol followup testing of an individual who has violated an FFD

policy and is consequently required to have at least 15 followup tests within the three-year period following the violation, and is transferring from one licensee's site to another. The proposed rule would require the receiving licensee or other entity to continue the followup testing program. However, the proposed rule would permit the licensee or other entity to accept the followup testing that was completed by the previous FFD program when determining the remaining number of followup tests to which the individual must be subject and the period of time during which the individual must continue to be subject to followup testing. Therefore, because the proposed rule would permit such reliance on other programs, more detailed requirements for conducting the activities upon which other FFD programs may rely, including drug and alcohol testing, are necessary to provide greater assurance that all Part 26 programs meet minimum standards. Third, at the public meetings discussed in Section V, industry stakeholders requested a greater level of detail in the specimen collection procedures of the proposed rule for the reasons discussed in Section IV. B.

Other major changes to the current rule's requirements for collecting specimens for drug and alcohol testing would be made to incorporate specimen validity testing requirements from the HHS Guidelines into Part 26 (Goal 1 of this rulemaking) and modify current alcohol testing requirements to improve the efficiency of FFD programs (Goal 3 of the rulemaking), while continuing to protect or enhance individuals' rights to privacy and due process under the rule (Goal 7 of the rulemaking).

Subpart F Licensee Testing Facilities

Subpart F [Licensee Testing Facilities] of the proposed rule would present detailed requirements for conducting initial urine specimen validity and drug tests at licensee testing facilities, as permitted in §26.24(d)(1) of the current rule and §26.31(d)(3)(i) of the proposed rule. The proposed subpart would be entitled, "Licensee Testing Facilities," for brevity, but

other entities who are subject to the proposed rule would be permitted to establish and operate such facilities under the proposed rule.

This new subpart would be added to group together in a single subpart the proposed requirements that are related to licensee testing facilities, which are intermixed with requirements related to drug testing at HHS-certified laboratories in Appendix A to Part 26 in the current rule. During the public meetings discussed in Section V, stakeholders requested that the proposed rule present the requirements that would be applicable to licensee testing facilities and HHS-certified laboratories in two separate subparts because, the stakeholders noted, it is not always clear which requirements apply to which type of testing facility in the current rule. The stakeholders also requested that any requirements that apply to both types of facilities would be included in both subparts so that it would be unnecessary for licensees and other entities who do not operate licensee testing facilities to review or implement any provisions in Subpart F. Although many of the requirements in this subpart would be redundant with similar requirements in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services], the proposed rule would implement these recommendations to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

The most important changes in proposed Subpart F to the current requirements for licensee testing facilities would be the addition of new requirements for licensee testing facilities to conduct urine specimen validity testing, based on similar provisions contained in the most recent revision to the HHS Guidelines (69 FR 19643; April 13, 2004). The reasons for requiring urine specimen validity testing are discussed in Section VI with respect to proposed §26.31(d)(3)(i). As discussed in Section V, stakeholders have objected to the addition of requirements for licensee testing facilities to conduct validity testing. However, the NRC believes that it is necessary for licensee testing facilities to conduct specimen validity testing

because Part 26 permits licensees and other entities to make authorization decisions based on initial drug test results from such facilities. Thus, licensees and other entities are permitted to grant authorization to an individual who has negative initial test results from pre-access testing without further analysis of the urine specimen by an HHS-certified laboratory. If the initial test results from the licensee testing facility are inaccurate because the urine specimen was adulterated or substituted, the licensee or other entity could grant authorization to an individual who poses a risk to public health and safety and the common defense and security. Similarly, if an individual who has been selected for random testing submits an adulterated or substituted specimen that is not detected by initial tests at the licensee testing facility, the individual would be permitted to maintain authorization if the results of drug testing are negative. Therefore, in order to increase the likelihood that individuals who may be using drugs and attempting to defeat the testing process are detected, and to ensure that they would not be permitted to be granted or maintain authorization, the NRC has concluded that it is necessary to require licensee testing facilities to conduct urine specimen validity tests.

However, in consideration of the increased costs and burden that are associated with instrumented initial validity testing, proposed Subpart F would permit licensee testing facilities to use non-instrumented validity testing devices to conduct “validity screening tests” of urine specimens, which may be a less expensive alternative than the instrumented initial validity tests required in the current HHS Guidelines. As discussed in Section VI with respect to proposed §26.5 [Definitions], the proposed rule would use the term, “validity screening test,” to refer to testing using these non-instrumented devices. The term, “initial validity test,” would refer to instrumented validity testing.

At the same time that the HHS published its final regulations to require specimen validity testing, which would be incorporated in the proposed rule, HHS also published a proposed revision to the Guidelines (69 FR 19673; April 13, 2004) that would permit the use of validity

screening devices for the detection of substitution and the presence of adulterants in urine specimens. These devices include non-instrumented devices with visually-read endpoints as well as semi-automated or automated instrumented testing devices with machine-read end points. Specimen validity tests conducted with these devices use colorimetric assays, which is the same scientific principle as the initial tests conducted at HHS-certified laboratories. Non-instrumented specimen validity devices for urine testing have been shown to detect adulterants in urine specimens and creatinine concentrations on tests that were conducted on specimens that were spiked with drug analytes. However, the results from the preliminary studies are variable. Therefore, the proposed HHS Guidelines include extensive performance testing requirements for these devices, which proposed Subpart F would also incorporate. Such performance testing is necessary to ensure that validity test results based on using these devices are accurate.

Subpart G Laboratories Certified by the Department of Health and Human Services

Subpart G [Laboratories Certified by the Department of Health and Human Services] in the proposed rule would present together in a single subpart requirements related to the HHS-certified laboratories that are used by licensees and other entities who are subject to Part 26 for validity and drug testing. The requirements in this subpart would group together the current requirements in Appendix A to Part 26, as they relate to HHS-certified laboratories. However, the current requirements would be updated to be consistent with the HHS Guidelines that were published in the Federal Register on April 13, 2004 (69 FR 19643). The most important changes to the current rule's requirements for HHS-certified laboratories would be the incorporation of extensive requirements for urine specimen validity testing.

Subpart H Determining Fitness-for-Duty Policy Violations and Determining Fitness

Subpart H [Determining Fitness-for-Duty Policy Violations and Determining Fitness] in the proposed rule would reorganize, clarify, and enhance current requirements related to the decisions that MROs and other healthcare professionals must make under Part 26 to provide input to licensees' and other entities' management decisions with respect to granting and permitting an individual to maintain authorization under proposed Subpart C [Granting and Maintaining Authorization] and also with respect to imposing sanctions and taking actions to prevent an individual from performing the job duties that require an individual to be subject to this part under proposed Subpart D [Management Actions and Sanctions]. The current requirements, which are interspersed throughout the rule, would be grouped together in the proposed subpart to make them easier to locate within the proposed rule, consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B. The proposed subpart would also make several significant changes to current requirements.

In general, proposed Subpart H would include more detailed requirements for determining FFD policy violations and conducting determinations of fitness than are included in the current rule. These more detailed requirements would be added in response to implementation questions that the NRC has received from licensees since Part 26 was first promulgated, "lessons learned" from NRC inspections of FFD programs, and the experience of other Federal agencies that similarly require workplace drug and alcohol testing. However, the NRC's primary concern in establishing more detailed requirements is to enhance the consistency in how FFD policy violations and fitness are determined among Part 26 programs. The proposed rule would permit licensees and other entities to rely on the determinations made by other Part 26 programs to a greater extent than the current rule. For example, proposed §26.63(b) would permit licensees and other entities to rely upon a previous licensee's or other

entity's determinations of fitness, as well as their reviews and resolutions of potentially disqualifying FFD information, for previous periods of authorization. The reasons for adding these permissions were discussed previously in this section, with respect to proposed Subpart C [Granting and Maintaining Authorization]. However, in order to ensure that all licensees' and other entities' determinations of FFD policy violations and fitness can be relied upon by other FFD programs, it is necessary to enhance the current requirements and establish clear minimum standards for those processes. Therefore, the proposed subpart would include greater detail to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

Under the proposed rule, licensees and other entities who are subject to the rule would continue to be prohibited from imposing sanctions on an individual who has a positive confirmatory drug test result from testing at the HHS-certified laboratory until the MRO has had an opportunity to discuss the result with the individual and determines that there is no legitimate medical explanation for the positive result(s). The proposed rule would extend this requirement to the review of non-negative validity test results, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed in Section VI with respect to proposed §26.31(d)(3)(i). An MRO review of non-negative confirmatory validity test results before a licensee or other entity imposes sanctions on an individual is necessary for the same reasons that an MRO review is required of positive drug test results. That is, there may be legitimate medical reasons for the non-negative test result and the test result may not indicate that the donor has violated the FFD policy, which in this case would mean that he or she has not attempted to subvert the testing process. Requiring the MRO to review non-negative validity test results would be added to meet Goal 7 of this rulemaking, which is to protect the due process rights of individuals who are subject to Part 26. The HHS Guidelines also require the MRO to review non-negative validity test results. Therefore, adding this requirement to the

proposed rule would also meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Another significant change that the proposed rule would make to current requirements is establishing a new position within FFD programs — the “substance abuse expert” (SAE). The SAE would be responsible for performing a determination of fitness, which is determining whether there are indications that an individual may be in violation of the licensee’s or other entity’s FFD policy or is otherwise unable to safely and competently perform his or her duties, in those instances in which an individual may not be fit for duty for reasons related to drug or alcohol abuse. The SAE position would be added for several reasons.

First, some MROs who provide services under Part 26 have indicated that they do not feel qualified to assess the presence and severity of substance abuse disorders, make treatment recommendations, and determine when an individual who has had a substance abuse disorder may again be able to safely and competently perform duties under this part. The focus of MRO responsibilities under Part 26 and other Federal workplace drug testing programs is on the medical evaluation of non-negative test results, which requires a knowledge of substance abuse. However, some MROs do not have the extensive knowledge of substance abuse disorders that is necessary to make determinations of fitness and treatment recommendations as required under this part. Therefore, the proposed rule would permit MROs to serve as SAEs if they meet the qualifications for this role that would be established in this subpart. But, licensees and other entities would be required to rely on other healthcare professionals who have the necessary qualifications to conduct determinations of fitness if the MRO does not meet the proposed SAE qualification requirements.

Second, during the meetings discussed in Section V, stakeholders requested that healthcare professionals, other than a licensed physician, be permitted to make determinations of fitness under the proposed rule. The stakeholders indicated that the costs of using only

licensed physicians are prohibitive and noted that a license to practice medicine does not guarantee that a physician is knowledgeable about substance abuse disorders. The NRC concurs that healthcare professionals other than licensed physicians may have the requisite knowledge and skills to serve as SAEs under the proposed rule. Therefore, the proposed rule would define the position of SAE in terms of the knowledge and skills required, and permit healthcare professionals other than licensed physicians to serve in this role.

Third, under the proposed rule, FFD programs would be permitted to accept determinations of fitness and treatment plans from other Part 26 programs, if an individual who has had a substance abuse problem will be granted authorization by another licensee or entity. Consequently, detailed requirements for the qualifications and responsibilities of the SAE are necessary to ensure consistency among FFD programs. Detailed requirements for the qualifications and responsibilities of the SAE are necessary because of the key role the SAE would play in assuring the common defense and security and public health and safety when making a determination of fitness upon which licensees and other entities will rely when making authorization decisions. It is critical that SAEs understand the potential impact on the common defense and security and public health and safety when determining that an individual who has had an active substance abuse problem has resolved the problem and is again worthy of the public's trust. A sophisticated understanding of substance abuse problems and the types of adverse behaviors they may involve, including knowledge of the research literature and clinical experience, is necessary to inform the SAE's clinical judgements in these circumstances.

Many of the provisions in the proposed subpart would be adapted from related DOT requirements regarding the "substance abuse professional" [49 CFR Part 40, Subpart O; 65 FR 41944; August 9, 2001]. The SAE role is not defined in current Part 26.

Subpart I Managing Fatigue

Subpart I [Managing Fatigue] of the proposed rule would strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue. Because the overall rationale for including Subpart I, Managing Fatigue, in Part 26, is detailed and extensive, this discussion is presented separately in Section IV. D.

Subpart J Recordkeeping and Reporting Requirements

Subpart J [Recordkeeping and Reporting Requirements] would be added to the proposed rule to reorganize the current rule's requirements for maintaining records and submitting reports to the NRC. The new subpart would combine and amend two sections of the current rule: Section 26.71 [Recordkeeping requirements] and §26.73 [Reporting requirements], and would incorporate the record retention requirements of current §§26.21(b), 26.22(c), and 26.80(c). This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, by grouping related requirements together in the proposed subpart.

Major changes to the current rule's requirements for recordkeeping and reporting would reflect (1) the addition of requirements for specimen validity to the proposed rule; (2) the addition of requirements for managing worker fatigue at nuclear power plants; and (3) a relaxation of the required frequency with which Part 26 programs must submit FFD program performance reports to the NRC from bi-annually to annually.

Subpart K Inspections, Violations, and Penalties

Subpart K [Inspections, Violations, and Penalties] would be added to the proposed rule to combine into one subpart current §§26.70 [Inspections], 26.90 [Violations] and 26.91 [Criminal penalties]. These sections would be grouped together in one subpart because they each establish requirements related to the NRC's oversight of the implementation of FFD programs. Proposed §26.221 [Inspections] would retain the requirements in current §26.70. Proposed §26.223 [Violations] would retain the requirements in current §26.90 [Violations]. Proposed §26.225 [Criminal penalties] would retain the requirements in current §26.91 [Criminal penalties].

D. Inclusion of Worker Fatigue Provisions in 10 CFR Part 26

The NRC has determined that the effectiveness of FFD programs in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security should be strengthened by establishing clear and enforceable requirements for the management of worker fatigue. Subpart I, Managing Fatigue, of the proposed rule would include these requirements and establish an integrated approach to fatigue management, with fatigue prevention, detection, and mitigation as the fundamental components. As discussed further in this section, the proposed requirements in Subpart I would provide a substantial increase in the protection of public health and safety and common defense and security. In determining the provisions of this proposed rule, the NRC has taken into consideration the effects of fatigue; the specific work practices of the nuclear power industry that contribute to and mitigate fatigue; the inadequacy of the current regulatory framework; the excessive hours currently worked by many nuclear power workers; and the practices of other industries and countries for regulating work hour limits. In addition, many public meetings were held with the

nuclear industry and the public to discuss draft provisions for the proposed rule. These interactions are discussed in detail in Section V of this document.

The NRC has determined that an integrated approach is necessary to effectively manage worker fatigue because individuals experience fatigue for many reasons, including long work hours, inadequate rest, and stressful or strenuous working conditions. Shiftwork, home-life demands, and sleep disorders can all contribute to inadequate sleep and excessive fatigue. Individual differences in worker tolerances to these conditions also influence worker fitness for duty. As a consequence, fatigue is a complex phenomenon that requires an integrated approach to be managed effectively. The requirements in proposed Subpart I were developed based upon the premise that fatigue management requires the collaboration of individual workers and licensees.

Each of the proposed requirements in Subpart I are discussed in detail in Section VI. However, because proposed Subpart I presents an integrated fatigue management approach, this section discusses the principal findings that led to the decision to include fatigue management provisions in Part 26, as well as supporting information on the causes and problems with worker fatigue in the nuclear power industry.

The Commission approved a rulemaking plan to include worker fatigue provisions for nuclear power plants in 10 CFR Part 26 on January 10, 2002, (SRM-SECY-01-0113), as described in Section I. Since that time, the NRC has continued to analyze the need for work-hour provisions in the proposed rule. The considerations listed in the numbered paragraphs that follow summarize the NRC's considerations concerning the appropriate regulatory action to address the potential for worker fatigue to affect public health and safety and the common defense and security. These considerations include:

(1) The research literature demonstrating the substantive effects of fatigue and decreased alertness on an individual's ability to safely and competently perform his or her duties;

(2) The prevalence of conditions that contribute to worker fatigue in the U.S. nuclear power industry;

(3) With the exception of orders limiting the work hours of security personnel, the NRC's current regulatory framework does not include consistent or readily enforceable requirements to address worker fatigue;

(4) Reviews of industry control of work hours have repeatedly identified practices that were inconsistent with the NRC's Policy on Worker Fatigue, including excessive use of work hours and work-hour limit deviations;

(5) The current regulatory framework includes requirements that are inadequate and incomplete for effective fatigue management;

(6) Ensuring effective management of worker fatigue through rulemaking would substantially enhance the effectiveness of FFD programs, but additional orders are not presently warranted to ensure adequate protection of public health and safety or the common defense and security; and

(7) Addressing the fatigue of workers in safety-critical positions through regulation is consistent with practices in foreign countries and other industries in the U.S.

Each of these considerations is discussed in greater detail below.

(1) Fatigue and decreased alertness can substantively degrade an individual's ability to safely and competently perform his or her duties.

The NRC previously noted in its "Policy Statement on the Conduct of Nuclear Power Plant Operations," dated January 24, 1989, (54 FR 3424), that "nuclear power plant operators on each shift must have knowledge of those aspects of plant status relevant to their

responsibilities to maintain their working environment free of distractions, and using all their senses, be alert to prevent or mitigate any operational problems." The degradation in an individual's cognitive functioning resulting from inadequate rest includes, but is not limited to, a reduced ability to sustain attention; maintain situational awareness; make timely and conservative decisions; communicate; and work effectively as a team member. Such degradations in performance, if exhibited by individuals performing risk-significant functions, can adversely affect the safety and security of a nuclear power plant.

The NRC has evaluated the research available on the degradation of worker abilities that are important to safe plant operation. The research supports the fatigue management provisions in Subpart I. Many of the specific research citations are listed in detail in Section VI. The following is a discussion of the fundamental concerns associated with worker fatigue, and some of the overall research that forms the basis for the integrated fatigue management approach in Subpart I.

Many studies have shown that fatigue impairs human alertness and performance (e.g., Alluisi and Morgan, 1982; Rosa, 1991; Scott, 1990; Dinges, 1992; Dinges, 1995; Dawson and Reid, 1997; Bobko, et al., 1998; Harrison and Horne, 2000; Williamson and Feyer, 2000). The lack of adequate days off and extended workdays (overtime) can result in a cumulative sleep debt (i.e., the difference between the amount of sleep an individual needs and the amount of sleep that individual actually obtains) and performance impairment (Webb and Agnew, 1974; Baker, et al., 1994; Colquhoun, et al., 1996; Tucker, et al., 1999; Williamson and Feyer, 2000; Department of Transportation (DOT), May 2, 2000, 65 FR 25546). Across a broad range of industries, studies concerning extended work hours suggest that fatigue-induced personnel impairment can increase human error probabilities by a factor of more than 2 to 3 times (Hanecke, et al., 1998; Colquhoun, et al., 1996; Akerstedt, 1995; U.S. DOT, 49 CFR Parts 350, et al., Proposed Rule, May 2, 2000, 65 FR 25544).

Studies of the nuclear power industry indicate that normal daily variations in alertness associated with human circadian rhythms (i.e., physiological processes that vary on an approximate 24-hour cycle) may be responsible for daily variations in the incidence of personnel errors at nuclear power plants (Bobko, et al., 1998; Dorel, 1996; Maloney, 1992). The findings of these studies are consistent with the results of a survey of more than 100 nuclear power plant shift supervisors — over 90 percent stated that they notice times of day, and days in the schedule, during which control room operators are less alert, less vigilant, or make more mistakes (Baker, et al., 1990 [EPRI NP-6748]). These studies suggest that, despite safeguards to ensure correct and reliable human performance, factors that influence alertness may increase the incidence of human errors in nuclear power plants.

Fatigue has generalized effects on human performance capabilities, and is associated with performance decrements at a base level, across a variety of tasks (Dinges, 1995). Fatigue can impair both physical and cognitive (i.e., mental) functioning.

Generally, cognitive task performance is affected more readily by fatigue than physical or psychomotor tracking performance (Krueger, 1989; 1991). General cognitive fatigue decreases an individual's ability to remain alert, process complex information, and correctly grasp a complex set of circumstances. Fatigue has been shown to cause memory problems, slowed responses, lapses and false responses (Williams, et al., 1959; Morgan, et al., 1974; Dinges, 1992; Dinges, 1995). Many of the cognitive tasks performed by nuclear power plant personnel that are important to the protection of public health and safety and the common defense and security rely on their ability to sustain attention, analyze, problems, make clear decisions, and communicate and work as a team. The following effects of fatigue on cognitive abilities are the primary focus of the proposed fatigue management requirements:

(a) Sustaining attention – Vigilance and attention to detail are fundamental for plant safety, whether an individual is operating or maintaining equipment important to plant safety, performing surveillance procedures in the plant, monitoring system status in the control room, or monitoring plant security systems or barriers.

Tasks requiring sustained attention (e.g., vigilance tasks) are among the most susceptible to fatigue-induced degradation (Monk and Carrier, 2003). The sensitivity to fatigue of vigilance tasks is one of the primary reasons that tests, such as the psychomotor vigilance task (Dinges, et al., 1997; Doran, et al., 2001), are standard measurement tools used in studies of the effects of sleep deprivation and fatigue. Of particular note are research findings showing that, in operational settings, individuals may experience periods of sleep up to a few seconds (called microsleeps), during which they fail to respond to external stimuli, and are completely unaware that these episodes have occurred (Cabon, et al., 2003; Priest, et al., 2001; Summala, et al., 1999).

(b) Decision-making – Conservative decision-making is a cornerstone of safe nuclear power plant operations. Fatigue has been associated with more risky strategies and decreases in the effort individuals exert (Schellekens, et al., 2000). Furthermore, Harrison and Horne (2000) reviewed the impact of sleep deprivation on decision-making and reported that, contrary to popular belief, sleep deprivation impairs decision-making even if individuals try to compensate for lack of sleep when responding to heightened stimulation. As noted by Cabon, et al. (2003), studies have shown reductions in aircrew alertness, even during the critical descent phase. These findings suggest that the alerting stimuli of off-normal conditions (e.g., landing an airplane, acknowledging control room annunciators) may not fully negate the effects of fatigue on performance. The National Transportation Safety Board (NTSB) reviewed the performance of flight crews involved in 37 major accidents and found that those crew members

who had been awake longer than 12 hours before their accidents made more errors overall, and specifically more tactical decision errors, than did crew members who had been awake for less time (NTSB, 1994).

(c) Problem solving – Perseveration is a term used to describe poor problem solving performance, characterized by an individual or group of individuals maintaining a faulty diagnosis or mitigation plan despite contrary information. An example of perseveration from the nuclear power industry was the initial response by plant operators to events at Three Mile Island Unit 2 in 1979. The operators' initial response was based on a faulty diagnosis of the plant condition (the operators failed to recognize they were dealing with a loss of coolant accident), which the operators maintained throughout the first 2 hours of the event in the face of numerous conflicting indications. Many factors contributed to human performance problems during the Three Mile Island accident and the NRC is not suggesting that operator fatigue was a contributing factor. However, fatigue is one factor that has been found to contribute to this type of performance degradation (Harrison and Horne, 2000), which may have serious consequences for public health and safety. Sleep-deprived workers fail to appropriately allocate attention, set task priorities, or sample for sources of potentially faulty information (Hockey, 1970; Krueger, 1989). Mental fatigue also contributes to decreased originality and flexibility in problem solving and sub-optimal planning (Van der Linden, et al., 2003; Lorist, et al., 2000; Horne, 1988).

(d) Communication and teamwork – Fatigue affects skills important to written and oral communication and teamwork. Fatigue degrades speech articulation, verbal fluency, grammatical reasoning (the ability to process oral and written instructions), and memory (Harrison and Horne, 1997; 1998). Studies of individuals in simulated combat and command and control conditions have shown that fatigue slows the encoding, decoding, and transcription

of information (Banderet, 1981; Angus and Heslegrave, 1985). Fatigued individuals also tend to be less communicative and have greater difficulty performing multiple tasks concurrently, as demonstrated in simulated aircraft cockpit tasks requiring monitoring and communications (Pascoe, et al., 1995; Harrison and Horne, 2000). These effects have been found in the analysis of incidents and accidents. In a study of major aircraft accidents, crews that had been awake longer (an average of 13.8 hours for captains and 13.4 hours for first officers) made significantly more procedural and tactical decision errors than crews that had been awake for a shorter period (an average of 5.3 hours for captains and 5.2 hours for first officers) (NTSB, 1994). Similar to control room personnel in nuclear power plants, aircraft cockpit crews make extensive use of secondary checks to verify that decisions and performance are correct, and to mitigate the consequences of errors. Although the difference was not statistically significant, analysis of the crew errors indicated that crews that had been awake longer made nearly 50 percent more errors in failing to challenge a faulty action or inaction by another crew member. These studies highlight how fatigue cannot only degrade the fitness of an individual, but also the overall performance of a crew.

Although fatigue has long been widely recognized as degrading performance, recent research has helped characterize the magnitude of these effects relative to a historical FFD concern: impairment from alcohol intoxication. The current provisions in 10 CFR Part 26 prohibit the use of alcohol on site and within several hours before a tour of duty, and establish alcohol testing requirements for personnel on duty. The NRC established these requirements based on the recognition that alcohol can have significant adverse effects on a worker's ability to safely and competently perform his or her duties. Recent studies have shown that fatigue can cause performance degradations that are comparable to the levels observed from blood alcohol concentrations (BACs) in excess of those that would result in a positive breath alcohol

test under the current provisions of 10 CFR Part 26. In those studies, individuals who were awake for 17–19 hours had cognitive and psychomotor performance comparable to individuals with a BAC of 0.05 percent (Dawson and Reid, 1997; Williamson and Feyer, 2000). Part 26 establishes a breath alcohol cutoff level of 0.04 percent. The NRC considers the insight that fatigue can impair a worker at levels comparable to those prohibited for alcohol to be particularly significant.

(2) Conditions that contribute to worker fatigue are prevalent in the U.S. nuclear power industry.

Fatigue may result from an individual remaining awake continuously for an excessive period of time, or from the individual obtaining an inadequate amount or quality of sleep, or both. Conditions that contribute to worker fatigue include:

(a) Extended work shifts with five or more consecutive work days – Although the effects of shift length on worker performance is influenced by the nature of the task, various studies have shown that task performance declines after 12 hours on a task (Rosa, 1991; Folkard, 1997; Dawson and Reid, 1997). Other studies have shown that the relative risk of having an accident increases dramatically after 9 consecutive hours on the job (Colquhoun, et al., 1996; Hanecke, et al., 1998; U.S. DOT, 49 CFR Parts 350, et al., Proposed Rule, May 2, 2000, 65 FR 25544). The effects of extended working hours on worker performance can be exacerbated when many extended shifts are scheduled in succession.

The use of 12-hour shifts has become increasingly common at U.S. nuclear power plants. Schedules that include 5 or more 12-hour shifts in succession during routine operations are sometimes popular with workers because they allow a long sequence of days off. However, scheduling more than 4 consecutive 12-hour shifts is not a recommended means of managing fatigue (Baker, et al., 1990 [EPRI NP-6748]; NUREG/CR-4248, “Recommendations for NRC

Policy on Shift Scheduling and Overtime at Nuclear Power Plants”). As noted in the 2000 Sleep in America Poll, “waking up unrefreshed" was more likely to be reported by individuals working more than 60 hours per week (58 percent vs. 42 percent of those working 41–60 hours per week and 39 percent of those working 31–40 hours) (National Sleep Foundation, 2000).

During the public meetings described in Section V, industry stakeholders noted that the use of 6 or more consecutive 12-hour shifts is now standard practice during plant outages. In SECY-01-0113, the NRC staff reported that more than 80 percent of the authorizations written by licensees to exceed the technical specification work hour limits during outages were for exceeding 72 hours (e.g., six 12-hour shifts) in a 7-day period. The NRC’s more recent review of deviations authorized at six plants for refueling outages during 2003 and 2004 also indicates that deviations from the limit of 72 hours in 7 days continue to account for more than 80 percent of the deviations authorized. During these meetings, industry stakeholders also reported that, during outages, some licensees have scheduled personnel for three or more weeks of consecutive 12-hour shifts without intervening days off.

(b) Extensive Overtime – Many research studies report that excessive working hours cause worker fatigue (Akerstedt, 1995b; Rosa, 1995; Buxton, et al., 2002). The U.S. nuclear power industry makes extensive use of overtime, creating a combined effect of long work hours with reduced break periods. As noted in SECY-01-0113, at approximately one-fourth of the sites, more than 20 percent of the personnel covered by working hour limits work more than 600 hours of overtime annually. This amount of overtime is more than two to three times the level permitted for personnel at some foreign nuclear power plants and more than twice the level recommended by an expert panel in 1985 (NUREG/CR-4248). In SECY-01-0113, the NRC also noted that some licensees authorized hundreds to several thousand deviations from the limits of 16 hours of work in any 24-hour period, 24 hours of work in any 48-hour period, 72-

hours of work in a 7 day period, and from the minimum break requirement of 8 hours between work periods. The NRC also noted the continued excessive use of such deviations in its survey of six plants in 2004.

(c) Shiftwork – The nuclear power industry is a round-the-clock operation requiring individuals to be awake and working at times when they would normally be asleep. Although individuals can function in these circumstances, human alertness and task performance are cyclically affected by a daily biological clock, which runs on about a 24-hour (circadian) cycle, as it assists in timing numerous physiological and psychological phenomena (such as core body temperature, the daily release of various hormones, mood swings, and wake-sleep cycle) (Liskowsky, et al., 1991). The circadian trough, or lowest levels of function reflected in, for example, alertness, performance, subjective mood, and body temperature, occurs around 3:00 a.m. to 5:00 a.m., with many human functions showing reduced levels between 12:00 a.m. and 6:00 a.m. Sleepiness is most severe between 3:00 and 5:00 a.m., with a less marked but significant expression again between 3:00 and 5:00 p.m.

There is a substantial scientific literature on circadian variations in alertness that clearly demonstrates the significant roles that worker fatigue, sleep loss, and circadian rhythms play in contributing to errors and accidents (Kryger, et al., 1994; Akerstedt, 1995a; Dinges, 1995; Folkard, 1997; Comperatore and Krueger, 1990; Miller and Mitler, 1997). These findings range from reduced response speed on a variety of tasks, to missing warning signals, to minor hospital incidents and accidents (Krueger, 1994). In addition, as previously described in this section, circadian variations have also been noted in studies of the incidence of personnel errors at nuclear power plants (Bobko, et al., 1998; Dorel, 1996; Maloney, 1992) and noted in observations by a large number of nuclear power plant shift supervisors (Baker, et al., 1990 [EPRI NP-6748]).

In addition to causing individuals to perform work at periods of depressed alertness, shiftwork also conflicts with circadian variations in alertness by requiring individuals to sleep during naturally occurring periods of increased cognitive arousal. Circadian rhythms, and naturally occurring tendencies for sleep and wakefulness, do not fully adapt to shiftwork schedules. In addition, daylight, noise and the "regular day" schedules of other family members challenge the ability of shiftworkers to obtain adequate rest. As a result, shiftworkers generally obtain less sleep, and report a higher incidence of sleepiness and sleep-related complaints. For example, in a survey of 1,154 U.S. adults, the National Sleep Foundation (NSF) found that shiftworkers, on average, get less sleep (6 hours, 30 minutes) than regular day workers (6 hours, 54 minutes). Almost half of the shiftworkers they surveyed obtained less than 6.5 hours of sleep per "night" during the work-week, 30-90 minutes less than recommended by most sleep experts. In comparison to regular day workers, shiftworkers were more likely to be sleepy at work 2 or more days per week (34 percent vs. 23 percent) (National Sleep Foundation, 2000). Many studies have demonstrated that decreased performance and increased errors and accidents are associated with night work and are affected by varying sleep schedules and durations of sleep periods (e.g., Balkin, et al., 2000).

The challenge for shiftworkers to remain alert during the early morning hours of a shift can be exacerbated by extended shift lengths, overtime, and the inability of many shiftworkers to obtain adequate sleep during the day (Hanecke, 1998). The powerful drive for sleep that is associated with circadian factors, and the fact that shiftwork is a daily influence on the alertness of all shiftworkers at nuclear power plants, has been demonstrated by a number of recent events. For example, there have been instances of operators falling asleep in the control rooms at the Pilgrim nuclear power station (2004) and the test and research reactor at the Massachusetts Institute of Technology (2003), as well as a security officer falling asleep at the

Braidwood nuclear power plant while driving a patrol vehicle (2004), despite these individuals recognizing the potential safety and disciplinary consequences.

(d) Early start times and extended commutes – Although many plant personnel do not work rotating shifts, start times before 7 a.m. can interfere with a worker's ability to obtain adequate rest if the schedule is not aligned with his or her circadian cycle and naturally occurring tendency for sleep and wakefulness. In addition, long commutes to remote work sites such as nuclear power plants, which are frequently located in rural areas and distanced from major population centers, contribute to the potential for fatigue associated with early start times.

(e) Sleep disorders – Sleep disorders, such as sleep apnea, insomnia, and restless leg syndrome (i.e., a condition that is characterized by uncomfortable or unpleasant sensations in the legs, causing an overwhelming urge to move them, often contributing to difficulty in staying or falling asleep), are conditions that can significantly reduce the quantity and quality of sleep that individuals are able to obtain, affect an individual's ability to remain alert, and ultimately degrade an individual's ability to safely and competently perform his or her duties (Kryger, et al., 1994; Lewis and Wessely, 1992). These factors are not effectively addressed by limits on working hours in the absence of other fatigue management practices. Although the NRC does not have data for the incidence of sleep disorders that is specific to U.S. nuclear power plant workers, in the general U.S. population, such conditions are not uncommon. For example, the prevalence of sleep apnea is estimated to be 4 percent for adult males and 2 percent for adult females (Strollo and Rogers, 1996). The incidence of sleep apnea may in fact be higher for shiftworkers at power plants, as this condition is more common in middle-age adult males than in the general population. A survey by the NSF of 1,154 adults living in households in the continental U.S. found self-reports of sleep apnea were more common from shiftworkers than regular day workers (15 percent vs. 9 percent) (National Sleep Foundation, 2000). Similarly,

the NSF found that shiftworkers reported a higher incidence of insomnia (66 percent vs. 55 percent) than regular day workers.

Although worker motivation can mitigate to a limited degree the effects of fatigue, fatigue has a physiological basis, including changes in glucose metabolism in the brain (Wu, et al., 1991; Thomas, et al., 2000), and such changes are beyond the individual's control. In addition, several studies have suggested caution with regard to the ability of individuals to self-monitor their abilities to safely and competently perform their duties when fatigued (Dinges, et al., 1997; Belenky, et al., 2003; Akerstedt, 2003). These studies note that individuals experience microsleeps without being aware of their lapses in attention and underestimate their propensity for uncontrolled sleep episodes. As a consequence, a worker's motivation to remain alert does not provide reasonable assurance that an individual will be able to safely and competently perform his or her duties.

Considering the above factors, the NRC believes that fatigue can have a significant adverse effect on worker abilities. Further, the likelihood of a nuclear power plant worker being impaired from fatigue is not trivial, and potentially greater than the likelihood of impairment from drugs and alcohol, which the NRC currently requires licensees to address through their FFD programs. Therefore, the NRC believes that regulatory action is warranted to ensure that fatigue is adequately addressed through licensee FFD programs. Further, the NRC believes that rulemaking is the appropriate regulatory action for the following reasons:

(3) With the exception of orders limiting the work hours of security personnel, the NRC's current regulatory framework does not include consistent or readily enforceable requirements to address worker fatigue.

The principal components of the current regulatory framework for matters pertaining to working hours and fatigue for non-security personnel are (a) NRC's Policy on Worker Fatigue,

as issued on June 15, 1982, in GL 82-12, and (b) plant technical specifications related to this policy statement, and (c) certain requirements of 10 CFR Part 26.

As part of the assessment of PRM-26-2, in which Barry Quigley petitioned for rulemaking to establish enforceable requirements addressing fatigue of workers at nuclear power plants, the NRC reviewed and assessed the implementation and enforceability of the NRC's current regulatory framework applicable to worker fatigue, including licensee technical specification requirements for the administrative control of work hours. This review was documented in detail in Attachment 1 to SECY-01-0113. The NRC continued this evaluation during development of this proposed rule, and the principal findings include:

(a) NRC's Policy on Worker Fatigue – NRC guidance documents do not prescribe requirements. Guidance documents establish policy or provide advice on meeting a regulatory requirement. As a result, the policy is enforceable only to the extent that the guidelines have been incorporated into a license condition or technical specification requirements. For the three nuclear power plant sites who have not incorporated the guidelines from the NRC's Policy on Worker Fatigue into a license condition or technical specification requirement, the guidelines are unenforceable. These plant sites have implemented the concept using other administrative controls that the NRC has determined to be adequate. However, had the NRC determined that the controls were inadequate, it would have no basis for taking enforcement action.

(b) Technical Specifications – For those licensees who have incorporated the NRC's Policy on Worker Fatigue into a license condition or technical specifications, consistent enforcement is complicated by the following factors:

– The language in plant technical specifications is largely advisory (e.g., an individual *should* not be permitted to work more than 16 hours straight) and key terms have not been defined. This deficiency results in inconsistent interpretation and implementation of technical

specification requirements by licensees, as well as difficulty for the NRC in enforcing the requirements. For example, many technical specifications use the terms, “routine heavy use of overtime,” “unforeseen problems,” and “temporary basis.” The NRC has not defined any of these terms and has not consistently pursued enforcement on the basis of the amount or frequency of overtime authorized.

– The technical specifications have inconsistent levels of detail from one nuclear power plant licensee to another. Only three-quarters of the licensees’ technical specifications include the quantitative working hour limit guidelines of the NRC’s Policy on Worker Fatigue.

– The technical specifications contain varying scopes of requirements. Some plant technical specifications require periodic reviews of overtime approvals to ensure that excessive hours have not been assigned, while other technical specifications contain no equivalent requirements. Although the observed variability in the controls does not by itself present a safety concern, such variability is inconsistent with establishing a uniform level of assurance that personnel are not in a fatigued condition that could significantly reduce their mental alertness and decision-making capability.

– Licensees have inconsistently interpreted the scope of personnel who must be subject to the technical specification work hour limits. The NRC’s Policy on Worker Fatigue applies to personnel who are performing safety-related functions. The NRC’s review of work hour data gathered by NEI regarding the work hours of personnel subject to the technical specifications (Nuclear Energy Institute, 2000) identified variation in the numbers and types of personnel covered by these controls. A limited number of sites may not be applying work hour controls to all personnel performing safety-related functions. At least two nuclear plant sites do not apply the work hour controls to any maintenance personnel even though GL 83-14, “Definition of Key Maintenance Personnel (clarification of GL 82-12),” issued March 7, 1983,

defined key maintenance personnel to include individuals who work on safety-related equipment.

– The basic measure used to determine whether an individual's work hours are within or above the technical specification limits is not implemented consistently from one nuclear power plant to another. Work hours included within the limits at some nuclear power plants are not included at others, effectively creating substantively different work hour limits among plants.

(c) 10 CFR Part 26, "Fitness for Duty Programs" – The general performance objectives of §26.10 require that licensees provide "reasonable assurance that nuclear power plant personnel . . . are not . . . mentally or physically impaired from any cause, which in any way adversely affects their ability to . . . perform their duties." Although 10 CFR Part 26 contains specific requirements pertaining to alcohol and drug usage, it does not include prescriptive requirements regarding fatigue. Rather, §26.20 uses general, non-mandatory language to state that the FFD policy "should" address other factors that can affect a worker's ability to safely and competently perform his or her duties, "such as mental stress, fatigue, and illness." As a result, it is difficult for the NRC to justify a violation of the regulation based on a licensee's failure to limit overtime hours. In addition, without a numerical limit on overtime hours, or a provision limiting overtime, a range of overtime practices could be viewed as "reasonable," and therefore in compliance with the regulation.

In summary, the broad and non-prescriptive provisions of Part 26, and the technical specifications and license conditions pertaining to fatigue, in the absence of clearly defined terms or measures of fatigue, make it difficult for the NRC to enforce worker fatigue requirements and working hours limits in an effective, efficient, and uniform manner that ensures that all licensees provide reasonable assurance that workers are able to safely and competently perform their duties. The NRC believes that a consistent fatigue management

program and its uniform implementation across the industry is essential, and the most effective regulatory mechanism is to incorporate worker fatigue into 10 CFR Part 26.

(4) Reviews of industry control of work hours have repeatedly identified practices that were inconsistent with the NRC's Policy on Worker Fatigue, including excessive use of work hours and work hour limit deviations.

The policy states, in part, "Enough plant operating personnel should be employed to maintain adequate shift coverage without routine heavy use of overtime." Surveys and expert panels have suggested that tolerance for overtime is generally limited to 300–400 hours of overtime per year (ADAMS Accession No. ML05270310; NUREG/CR-4248). Baker, et al. (1994) reviewed the hours worked by nuclear power plant operations, technical, and maintenance personnel during 1986, four years after the NRC issued its policy. Based on a sample of 63 percent of U.S. nuclear power plants operating at that time, Baker and colleagues found that operations personnel averaged more than 500 hours of overtime annually at 20 percent of the plants, and more than 700 hours of overtime at 9 percent of the plants. Technical personnel averaged more than 500 hours of overtime annually at 30 percent of the plants, and more than 700 hours of overtime at 18 percent of the plants. Maintenance personnel averaged more than 500 hours of overtime annually at 80 percent of the plants and more than 700 hours of overtime at 14 percent of the plants.

The NRC's Policy on Worker Fatigue includes provisions for licensees to authorize deviations from the NRC's work and rest guidelines for individual workers in "very unusual circumstances." On June 10, 1991, following several NRC inspections noting concerns related to licensee work hour control, the NRC issued Information Notice (IN) 91-36, Nuclear Power Plant Staff Working Hours, to alert licensees of potential problems resulting from inadequate controls to prevent excessive working hours. The conditions cited in the notice included an

event attributed to fatigue, excessive use of deviations and overtime, and overtime deviations authorized after the fact. Subsequent NRC reviews completed in 1999 and 2001 have identified continued problems with industry control of work hours. In 1999 the NRC reviewed licensee event reports and NRC inspection reports from January 1994 through April 1999. The NRC found that only a few events of limited risk significance had been attributed to fatigue. However, the staff found several instances each year in which licensee use of overtime appeared to be inconsistent with the general objectives or specific guidelines of the NRC's Policy on Worker Fatigue.

The Nuclear Energy Institute (NEI) conducted a survey in the summer of 2000 concerning industry control of work hours for personnel subject to the technical specification requirements (letter dated August 29, 2000, from J. W. Davis, NEI, to G. T. Tracy, NRC, ADAMS Accession No. ML003746495). Forty-seven sites responded to the survey, providing data from 1997–1999. The NRC staff's review of the data is documented in Attachment 1 to SECY-01-0113. The NRC evaluated the results of the survey concerning overtime and found that 8 of 36 sites providing data had more than 20 percent of the personnel covered by the policy working in excess of 600 hours of overtime per year. Considering all plants that provided data, the percentage of personnel working in excess of 600 hours of overtime increased from 7 percent in 1997 to 11 percent in 1999. The percentage of licensed operators working in excess of 600 hours increased from 13 percent in 1997 to more than 16 percent in 1999. The NRC believes these percentages represent excessive use of overtime in the nuclear industry.

The NRC also reviewed the data collected by NEI concerning deviations, which showed that approximately one-third of the respondents were authorizing more than a thousand, to as many as 7,500, deviations in a year to exceed the policy guidelines. The frequency of deviations did not appear to be consistent with either the specific guidelines or the general

objective of the policy. As previously described in this section, the policy permits deviations from the guidelines in "very unusual circumstances."

Subsequent to the Commission's decision to initiate rulemaking for worker fatigue, the NRC staff also obtained data from six sites in 2004. Those data indicated that between 95 and 603 deviations, with an average of 311 deviations, were issued for individuals. The data were provided by the six sites for each plant's most recent refueling outage and one month of power operation, and therefore do not reflect the total number of deviations issued for individuals during all of 2004, except for one of the six sites that provided its deviation data (101 deviations) for all of 2004. Data on the deviations from 2004 are reported in detail in Appendix 3 of the draft Regulatory Analysis. The analysis is available as discussed above under the "ADDRESSES" heading. Single copies may be obtained from the contact listed above under the "FOR FURTHER INFORMATION CONTACT" heading. The NRC believes that licensee use of deviations and overtime at some sites is excessive, and does not represent the intent of the NRC's Policy on Worker Fatigue.

In addition to excessive work hours and work hour guideline deviations, the NRC has recently identified other concerns related to licensee policies and practices applicable to worker fatigue. On May 10, 2002, the NRC issued Regulatory Issue Summary (RIS) 2002-007, "Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declaration of Fitness-For-Duty." The NRC issued the RIS following several allegations made to the NRC regarding the appropriateness of licensee actions or policies related to individuals declaring they are not fit due to fatigue. These concerns indicate a need to ensure that individuals and licensees clearly understand their responsibilities with respect to self-declarations of worker fatigue. The proposed rule would establish requirements to address this need.

(5) The current regulatory framework includes requirements that are inadequate and incomplete for effective fatigue management.

a. The NRC's Policy on Worker Fatigue did not establish clear expectations for the control of work hours. As previously noted in this section, the NRC did not define key terms of the policy, and, as a consequence, implementation has been varied across the industry.

b. Certain policy guidelines and technical specification requirements are inadequate for reasonable assurance that individuals remain capable of safely and competently performing their duties. For example, the requirement for an 8 hour break between work periods would be revised to a 10 hour break. The basis for the need to revise this break period is described in detail in Section VI with respect to proposed §26.199(d)(2)(i).

Further, the specific work hour guidelines of the policy, and most technical specification requirements for the administrative control of work hours, are principally focused on acute fatigue, and do not adequately address the longer term control of work hours and the cumulative fatigue that can result from prolonged periods of extended work hours. Acute fatigue results from restricted sleep, sustained wakefulness, continuous task demands, or other issues over the past 24 hours or more. Cumulative fatigue results from inadequate rest over consecutive sleep-wake periods when the worker obtains less sleep than he or she requires. An individual incurs a sleep debt for each day or night during which the worker obtains insufficient sleep. If the individual continues to obtain insufficient sleep, this debt accumulates over successive days, resulting in increasing fatigue and impairment (Belenky, et al., 2003).

The inadequacy of the current regulatory framework for addressing cumulative fatigue became particularly apparent in the months following the terrorist attacks of September 11, 2001. As described in Section VI with respect to proposed §26.199(f)(2), the NRC received numerous allegations from nuclear security officers that certain licensees

required them to work excessive amounts of overtime over long periods due to the post-September 11, 2001, threat environment. These individuals questioned their readiness and ability to perform their required job duties due to the adverse effects of cumulative fatigue. The NRC reviewed the actual hours worked by security personnel and determined that, in the majority of cases, individual work hours did not exceed the guidelines specified in the NRC's Policy on Worker Fatigue, but the review confirmed that individuals had been working up to 60 hours per week for extended periods. The concerns expressed by individuals regarding their FFD, in light of work schedules that did not exceed the specific guidelines of the policy, as well as relevant technical research supporting the basis for cumulative fatigue, led the NRC to conclude that the work hour guidelines of the policy are inadequate for addressing cumulative fatigue. The NRC obtained additional worker feedback supporting this conclusion through a review of worker fatigue concerns and work hours during a long-term outage at the Davis Besse nuclear plant (NRC Inspection Report 05000346/2004003, dated March 31, 2004, ADAMS Accession No. ML040910335).

The comprehensive fatigue management approach in Subpart I, Managing Fatigue, would establish controls to address cumulative fatigue. Limits to mitigate cumulative fatigue for security personnel were implemented by Order EA-03-038. The proposed rule would codify, with limited changes, these requirements. Changes to those limits that would be imposed by this rule are discussed in detail in Section VI, which also includes a detailed discussion of the proposed limits and other controls to mitigate cumulative fatigue for non-security personnel.

c. The existing regulatory framework does not effectively ensure that fatigue from causes other than work hours is addressed. Work hour controls are necessary, but not sufficient, to effectively manage worker fatigue. As a consequence, training and fatigue assessments are essential. Worker fatigue, and its effects on worker alertness and

performance, can result from many causes in addition to work hours (e.g., stress, sleep disorders, daily living obligations) (Rosa, 1995; Presser, 2000). In addition, there are substantial individual differences in the ability of individuals to work for extended periods without performance degradation from fatigue (Gander, 1998; Van Dongen, et al., 2004a; Van Dongen, et al., 2004b; Jansen, et al., 2003). Proposed Subpart I, Managing Fatigue, would require a comprehensive fatigue management program. One example would be the strengthening of FFD training requirements concerning worker fatigue. This would improve behavioral observation and assessment of worker fatigue, self-declaration as a means for early detection of fatigue, worker self-management of fatigue, the ability of workers to obtain adequate rest on a shiftwork schedule, and licensee use of effective fatigue counter-measures.

(6) Ensuring effective management of worker fatigue through rulemaking would substantially enhance the effectiveness of FFD programs, but additional orders are not presently warranted to ensure adequate protection of public health and safety or the common defense and security.

Adequate protection of public health and safety and the common defense and security are ensured under the current regulatory framework, including Order EA-03-038 (for security personnel), the NRC's Policy on Worker Fatigue, and licensee technical specification requirements. Licensee FFD programs currently include behavioral observation programs to identify individuals whose behavior indicates they may not be fit to safely and competently perform their duties, and ensure that those individuals are removed from duty until any question regarding their fitness has been resolved. The current work hour controls, in conjunction with licensee behavioral observation programs, automatic reactor protection systems and other administrative controls on worker activities (e.g., post-maintenance testing, peer checks, independent verifications) ensure adequate protection of public health and safety and the

common defense and security. However, there are substantial limitations to the current regulatory framework, as detailed in this section. Therefore, although the current regulatory framework provides adequate protection, including work hour controls in 10 CFR Part 26 would provide a substantial increase in public health and safety and the common defense and security. The NRC is proposing to incorporate worker fatigue provisions into Part 26 in light of the substantial increase in safety and security that is expected to result.

(7) Addressing fatigue of workers in safety-critical positions through regulation is consistent with practices in foreign countries and other industries in the U.S.

The NRC reviewed the current and proposed Federal limits on work hours for nuclear plant workers in eight other countries, as well as six other industries in the United States and Canada. Although many factors influence specific regulatory limits, and requirements for other industries should be considered in context, the NRC found that the NRC's current guidelines are the least restrictive among those reviewed.

The work hours of nuclear power plant personnel in other countries are largely based on labor laws or union agreements. With the exception of Spain, which has limits consistent with the NRC's Policy on Worker Fatigue, each of the other eight countries has more stringent requirements. The more stringent requirements have largely preempted the need in those countries for regulation of work hours based on nuclear safety concerns.

The Department of Transportation (DOT) has established regulatory limits on the work hours of pilots, air traffic controllers, and maintenance personnel in the commercial aviation industry (14 CFR Parts 121 and 135), in the maritime industry (46 U.S.C. 8104; 46 CFR Parts 15.705, 15.710 and 15.111), in the rail industry (49 U.S.C. 211; 49 CFR Part 228), and for drivers of heavy trucks in the commercial trucking industry (49 CFR Part 395). The DOT recognized that fatigue can substantively degrade the ability of individuals to perform these

duties and, therefore, promulgated regulatory requirements for each of these modes of transportation in keeping with the department's mission to protect public safety. In the late 1980s and early 1990s, the National Transportation Safety Board (NTSB) identified equipment operator fatigue as a significant issue affecting all transportation modes (Beal and Rosekind, 1995). As a result, DOT classified operator fatigue management as a DOT "Flagship Initiative" and several proactive fatigue management activities ensued across the transportation industries (e.g. U.S. DOT, 1995; Rogers, 1996, 1997; Hartley, 1998; Carroll, 1999).

In 1999, the NTSB evaluated DOT's decade of efforts on operator fatigue (NTSB, 1999). Dissatisfied that enough was being done, NTSB subsequently offered DOT three recommendations: (1) expedite a coordinated research program on the effects of fatigue, sleepiness, sleep disorders, and circadian factors on transportation safety; (2) develop and disseminate educational materials for transportation industry personnel and management regarding shift work, work rest schedules, and proper regimens of health, diet, and rest; and (3) review and upgrade regulations governing hours of service for all transportation modes to assure they are consistent and incorporate the results of the latest research on fatigue and sleep issues (NTSB, 1999).

On April 28, 2003, the DOT issued revised hours-of-service regulations to require motor carriers to provide drivers with better opportunities to obtain sleep. Among other provisions, the regulations (1) increase the required off-duty time from 8 to 10 consecutive hours; (2) prohibit work after the end of the fourteenth hour after the driver began work; and (3) require long break recovery periods to prevent cumulative fatigue (68 FR 22456-22517; April 28, 2003).

Nuclear power plant licensees in the U.S. have sometimes asserted that the characteristics of the work tasks in nuclear power plants differ from other occupations that have work hour controls (e.g. transportation equipment operators); therefore information from other

occupations may not be applicable. In addition, licensees have suggested that the level of automation in nuclear power plants provides an important barrier to human errors resulting from fatigue, and that the amount of control room crew interaction and oversight of operators' actions assures that fatigue-induced errors will be detected and corrected before they have an opportunity to impact plant operations. The NRC concurs that requirements for other industries should be considered in context. Nevertheless, the fact that other federal agencies with a safety mission have established regulations to address fatigue is relevant for several reasons.

First, the human need for sleep and the deleterious effects of sleep deprivation have a physiological basis (e.g., changes in brain glucose metabolism) that is independent of the nature of the work being performed (Wu, et al., 1991). Second, circadian variations in alertness and performance, and the underlying changes in physiological processes, have been observed in individuals performing a wide range of tasks across many industries (Kecklund, et al., 1997). For all individuals, time since awakening, the time of day, and the amount of prior sleep that an individual obtains relative to his or her sleep needs are primary determinants of fatigue and the need for sleep.

The NRC acknowledges that task characteristics and time on task may exacerbate the effects of fatigue on the ability of individuals to remain alert. For example, a concern for task-specific effects is reflected in the DOT hours-of-service regulations for commercial truck drivers, which establish a daily limit on driving time of 11 hours per day. This limit is in addition to the requirements prohibiting driving after 14 hours on duty and mandating minimum 10-hour break periods, which reflect the human physiological need for rest that is necessary to maintain performance (68 FR 22456-22517; April 28, 2003).

By comparison to driving a truck, the characteristics of some jobs in nuclear power plants (e.g., reactor operator) permit greater freedom of movement and social interaction, which

may serve to temporarily mitigate the effects of fatigue on alertness. However, there is no evidence to indicate that worker motivation or the stimulating effects of the job or environment alter the underlying physiological processes. Although crew interactions and other job characteristics may serve to bolster worker alertness temporarily, environmental stimulation only masks individuals' physiological need for sleep. Removing the stimulation (e.g., transitioning from the activity of shift turnover to monitoring steady state plant operations during a night shift) will increase the potential for lapses in attention and uncontrolled sleep episodes among individuals who may be partially sleep deprived or otherwise fatigued.

Another consideration regarding the relevance of other regulations limiting work hours is that adverse fatigue effects are observed across a broad range of cognitive functions in addition to alertness. Whereas crew interactions may help sustain alertness, sleep deprivation and sustained periods of wakefulness continue to degrade other cognitive functions (e.g., memory and decision making) and elements of performance that are important to safe nuclear plant operations, such as communications and following written and oral instructions. For example, as discussed in paragraph D(1)(d) of this section, studies of crew performance in critical phases of commercial aircraft flight (e.g., take-off and landings) and in simulated battle command station operations have shown fatigue-related degradations in performance despite the stimulation of the interactions, the intense level of activity, and the implications of degraded performance for the loss of human life. Regulations limiting work hours in other industries that use operating crews (e.g., aviation) and allow greater freedom of movement than trucking (e.g. maritime) are consistent with this understanding of the broad effects of fatigue on cognitive performance. There is no reason to believe that nuclear power plant workers' physiological processes and the adverse effects of fatigue on their abilities to perform their job tasks would differ. In addition, the notion that human performance practices in the nuclear industry prevent

fatigue-related performance decrements from resulting in human errors is not supported by studies that have shown circadian variations in performance at nuclear power plants (Bobko, et al., 1998; Dorel, 1996; Maloney, 1992).

The NRC acknowledges that the nuclear power industry is perhaps unique, relative to many other industries, in its use of automated safety systems to protect against the consequences of equipment failure and human error. Nevertheless, reliable human performance remains an essential element in the protection of public health and safety and the common defense and security. Current NRC requirements, such as the minimum on-site staffing requirements of 10 CFR 50.54(m) and minimum security staffing requirements in site security plans, are predicated on the expectation that all personnel in these positions are fit for duty and are able to safely and competently perform their duties. As a consequence, the NRC does not consider the use of automated safety systems to be an appropriate basis for permitting conditions that could allow fatigue to degrade the important line of defense of reliable human performance. Further, despite automated systems, the contribution of human error to risk in operating events continues to be notable (NUREG/CR-6753, “Review of Findings for Human Error Contribution to Risk in Operating Events”).

Because the NRC concurs that task characteristics are an appropriate consideration, the proposed rule would differ from other Federal agencies’ requirements with respect to specific work hour requirements and would require licensees to consider task characteristics when authorizing any waiver from the work hour controls. Nevertheless, the NRC believes that it remains relevant that other Federal agencies with public safety missions have chosen to address worker fatigue through regulation.

In summary, the NRC believes that the proposed requirements in Subpart I will provide a substantial increase in the protection of public health and safety and common defense and

security. In determining the provisions of this proposed rule, the NRC has taken into consideration the effects of fatigue on human performance, the specific work practices of the nuclear power industry that both mitigate and contribute to fatigue, the inadequacy of the current regulatory framework, the excessive hours currently worked by many nuclear power plan personnel, and the relevant research and practices of other industries and countries for regulating work hour limits. In addition, many public meetings were held with the nuclear industry and the public to discuss draft provisions for the proposed rule. These interactions are discussed in detail in Section V. The specific basis for each provision of the fatigue management portions of the proposed rule are discussed in Section VI.

The proposed requirements for managing fatigue will provide a substantial increase in the protection of public health and safety and common defense and security by:

(1) Establishing specific, integrated, comprehensive, and enforceable requirements for the effective prevention, detection, and mitigation of worker fatigue;

(2) Ensuring that personnel who perform functions that are significant to the protection of public health and safety or the common defense and security are subject to appropriate work hour controls, including: individuals performing risk significant operations or maintenance duties; health physics, chemistry, and fire brigade duties important to emergency response; and individuals performing security duties important to maintaining the security of the plant;

(3) Establishing work hour controls that provide increased assurance that workers will have adequate opportunity for rest and that deviations from the work hour limits will only be authorized as necessary for plant safety or security and following appropriate assessment of the worker's ability to safely and competently perform his or her duties;

(4) Ensuring that work hour deviations are only permitted when necessary for plant safety or security, and following assessment of the worker's ability to safely and competently perform his or her duties;

(5) Establishing controls to prevent cumulative fatigue that can result from consecutive weeks of extended work hours;

(6) Ensuring workers are provided with sufficient break periods to provide for adequate opportunity for sleep to mitigate acute and cumulative fatigue;

(7) Ensuring that, in addition to work hours, other factors that can affect worker fatigue and the ability of workers to remain alert are adequately addressed through licensee FFD programs;

(8) Encouraging effective fatigue management by permitting licensees to use alternate measures for prevention and mitigation of fatigue; and

(9) Strengthening FFD training requirements concerning worker fatigue. This would improve behavioral observation and assessment of worker fatigue; self-declaration as a means for early detection of fatigue; worker self-management of fatigue; the ability of workers to obtain adequate rest on a shiftwork schedule; and licensee use of effective fatigue counter-measures.

V. Summary of Public Interactions and Comments

In preparing this proposed rule, the NRC has considered comments received by OMB and the NRC on the prior Part 26 final rule affirmed by the Commission in a SRM dated December 4, 2000, and subsequently submitted to the Office of Management and Budget (OMB) for a clearance under the Paperwork Reduction Act. Those comments and responses to them are provided in Section V. A.

The NRC has also considered feedback received from industry, as well as other interested parties and members of the public in preparing this proposed rule. The NRC held 11 stakeholder meetings on the drug and alcohol testing portions of the rule during 2001–2004, and held 13 stakeholder meetings on the fatigue portion of the rule during 2002–2003. Subsequent to the Commission's decision to combine the two rulemaking efforts, the NRC held 1 stakeholder meeting on the combined rule in July, 2004, and 2 subsequent meetings on the fatigue provisions of the combined rule in August and September, 2004.

Throughout the time the meetings were being held, drafts of proposed rule language, regulatory and backfit analysis data, and other pertinent information were made available to the public on the internet ,as announced in the Federal Register (67 FR 7093) on February 15, 2002. Feedback was received from stakeholders both through the public meetings and the NRC's rulemaking website at http://ruleforum.llnl.gov. Summaries of these meetings, and any comments provided through the website are available at http://ruleforum.llnl.gov/cgi-bin/rulemake?source=BQ_PETITION&st=plan for meetings and comments on the fatigue portions of the rulemaking prior to 2004, and at http://ruleforum.llnl.gov/cgi-bin/rulemake?source=Part26_risk&st=risk for meetings and comments on the drug and alcohol testing portions of the rulemaking, and on the fatigue portions of the rulemaking subsequent to the Commission's decision to combine the rulemakings in 2004. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; email cag@nrc.gov.

These interactions with stakeholders were a significant benefit to the NRC in developing the language for the proposed rule in a manner to ensure it was clearly understandable, could be consistently interpreted, and did not result in unintended consequences. Many of the

stakeholders' comments directly resulted in proposed changes. Where a comment was included in a proposed provision, the comment is discussed in Section VI.

Many comments were received during the years the meetings were held, and the draft proposed rule language was changed and re-posted to the web numerous times. Each comment received during these meetings, but not included in the proposed rule text, is not discussed and responded to in detail, given that the NRC is issuing a new proposed rule for formal public comment. However, the most significant comments that were not incorporated are discussed in Section V. B of this document.

A. Public Comments Submitted to OMB on 2000 Final Rule and Responses

The comments below were received by OMB and the NRC on the prior Part 26 final rule affirmed by the Commission in a SRM dated December 4, 2000, and subsequently submitted to OMB for a clearance under the Paperwork Reduction Act. The NRC's responses follow each comment.

Industry Comment 1: Rule should allow combining partial samples to get the required volume for HHS analysis. Otherwise, it [the Regulatory Analysis] should reflect an added expense with a reduced gain.

Response: New provisions in §26.109, "Urine specimen quantity," prohibit licensees from combining partial samples because this practice may falsely lower the concentration of a drug or adulterant. Further, HHS and DOT do not permit this practice. Additionally, comments on the previous proposed rule objected to combining specimens for the same reason. However, the proposed rule would lower the required specimen quantity from a minimum of 60 milliliters (mL) to 30 mL. NRC discussions with representatives of HHS-certified laboratories

have indicated that advances in testing technologies allow accurate and reliable testing of 15 mL specimens. The NRC has proposed 30 mL, which would allow the HHS laboratory sufficient specimen quantity for retesting, if needed. Because the required specimen quantity has been reduced by at least one-half, there should be few instances in which a donor is unable to produce the necessary quantity and, therefore, few instances in which additional costs would be incurred.

Industry Comment 2: Medical professionals other than a licensed physician should be allowed to determine if a history of substance abuse "raises a concern."

Response: The proposed rule in §26.187 would add a position called the "Substance Abuse Expert" (SAE), adapted from the related DOT regulations. The SAE need not be a licensed physician, but would be required to have extensive expertise, such as a licensed or certified social worker, psychologist, or others listed in §26.187(b), and additional qualifications specifically related to substance abuse disorders. The SAE would be authorized to make a determination of fitness in at least circumstances: (1) when an individual has violated the substance abuse provisions of a licensee's or C/V's FFD policy, including, but not limited to a first positive drug test result; (2) when there is a concern that an individual may be impaired by the use of a substance; or (3) for an applicant for authorization when the self-disclosure, the suitable inquiry, or other sources of information identify potentially disqualifying FFD information (PDFFDI) about the applicant.

Industry Comment 3: Reevaluate NRC's regulatory analysis indicating a $27 million savings in light of industry's estimate of a $8 million cost increase.

Response: A detailed reevaluation of the drug and alcohol provisions, based in part on data obtained from NEI, still indicates a savings to industry of $116 million - $183 million (7 percent - 3 percent discount rate) present value. The evaluation of the proposed Part 26

provisions as a whole, including the proposed worker fatigue provisions, indicates a cost to industry of $469 million - $730 million (7 percent - 3 percent discount rate) present value. A draft regulatory analysis was provided to industry and other stakeholders during the public meetings held in 2004. Comments received have been considered in developing the regulatory analysis for this proposed rule.

Industry Comment 4: New rule requires audits of [HHS] certified labs.

Response: The proposed rule includes additional language in proposed §26.41 to clarify the NRC's intent that audits of certified labs may be shared among licensees and that licensees are not required to audit areas that are covered by the HHS certification process. Additionally, organizations that do not routinely provide FFD services to a licensee or C/V, such as local hospitals or a substance abuse treatment facility, would be exempt from the annual audit requirement.

Industry Comment 5: Rule includes FFD personnel in program.

Response: The NRC continues to agree with the original intent of the rule, which was that personnel who administer FFD programs must be covered by 10 CFR Part 26. However, during meetings, stakeholders discussed the numerous logistical difficulties associated with covering FFD program personnel. As a result, the proposed rule includes a number of related language adjustments.

Specifically, new language in proposed §26.25(a)(4) would clarify the NRC's intent that FFD program personnel must be subject to the program. Proposed §26.25(a)(4)(i) through (v) would be added to identify the FFD program personnel who must be subject to the FFD program, based upon their job responsibilities. Proposed §26.25(b)(1) would exempt individuals who may provide an FFD service to a licensee or other entity in special circumstances, and who meet all of the following three criteria: (1) they are not employed by the

licensee or C/V, (2) they do not routinely provide services to the licensee's or other entity's FFD program, and (3) they do not normally work at a licensee or other entity's facility. Personnel who meet the three criteria specified in proposed §26.25(b)(1) would be exempt because the limited nature of their involvement with the FFD program makes it unlikely that they would be subject to coercion or influence attempts to subvert the testing process.

In addition, new language in §26.31(b)(2) would permit FFD program personnel who are distant from a licensee site to be tested at a local facility that meets DOT requirements, including audits. Permitting these FFD program personnel to be tested at local collection sites that follow similar procedures would be adequate to meet the goal of ensuring their continuing honesty and integrity, while addressing some logistical concerns posed by stakeholders.

Industry Comment 6: The term, "history of substance abuse," is pejorative and may incorrectly label some workers in the nuclear industry as substance abusers.

Response: Based upon further discussions with stakeholders, the NRC developed a greater appreciation for the connotations of the term, "history of substance abuse," and agreed that the term has too many pejorative implications. Therefore, the proposed rule would entirely eliminate the use of this term. The rule language no longer discusses this issue in terms of an individual's personal characteristics. Rather, the language focuses on the type of information that would trigger a determination of fitness. This information is referred to as "potentially disqualifying FFD information" (PDFFDI), which is consistent with terminology used in access authorization programs.

Industry Comment 7: History of substance abuse creates a new class of workers and no relief.

Response: As noted above, the concept, "history of substance abuse," has been eliminated in the proposed rule. The proposed rule would provide relief to individuals with

PDFFDI in three ways. First, individuals would be required to self-disclose PDFFDI that is related to events that occurred only within the past 5 years. This provision provides relief from the current rule, which requires individuals to self-disclose certain adverse events every time they apply for authorization, no matter how long ago the adverse events occurred. Second, licensees would be permitted to accept a determination of fitness conducted by a previous licensee and a favorable termination of authorization for an individual who had any PDFFDI that was addressed and resolved under a previous Part 26 program. This provision also provides relief from the current rule, which requires the licensee to conduct a determination of fitness for any individual who has ever been denied access or had access terminated unfavorably, no matter how long ago the event occurred or whether there is evidence that the individual has been rehabilitated. Licensees would be permitted to conduct another determination of fitness, but would not be required to do so, if the individual's last period of authorization was terminated favorably. Third, licensees would be permitted to accept responsibility for continuing any treatment and followup testing plans that a previous licensee implemented for an individual, rather than conducting a new determination of fitness and developing new treatment and testing plans. These provisions protect the rights of individuals who have successfully resolved or are resolving a substance abuse-related problem as well as reduce the regulatory burden on the individuals and licensees.

Industry Comment 8: History of substance abuse creates a tracking burden.

Response: As noted above, the concept, "history of substance abuse," would be eliminated in the proposed rule. Further, the current rule requires licensees to maintain records and share information related to denials and unfavorable terminations of authorization in §26.27(a)(3). Therefore, the proposed rule's requirements for licensees to maintain records

and share information related to PDFFDI would not create a new tracking burden and are consistent with the access authorization Order.

Industry Comment 9: Change the opiate cutoff level of 300 ng/mL to the HHS standard of 2000 ng/mL.

Response: The proposed rule now includes the 2000 ng/mL HHS cutoff level for opiates. Discussions with HHS indicate that the HHS staff's rationale for changing the cutoff level to 2000 ng/ML provides sufficient protection for public health and safety from individuals who may be abusing opiates.

Industry Comment 10: It is impossible to complete all suitable inquiries within 72 hours.

Response: Consistent with the access authorization Order, which the Commission issued to nuclear power reactor licensees on January 7, 2003, the proposed rule would eliminate provisions for routine temporary access. Therefore, the proposed rule would eliminate the requirement in the Affirmed Rule for a 72-hour turnaround on a suitable inquiry prior to granting temporary access.

Industry Comment 11: Rule requires verification of all employment periods, including less than 30 days.

Response: The proposed rule incorporates feedback received through stakeholder meetings. The revised provisions specify employers required to be addressed during the suitable inquiry for several different cases, including applicants for initial authorization, updated authorization, or reinstated authorization. The employers required to be addressed vary for each of these situations, and are specified in proposed §§26.63 and 26.69. In developing this proposed section, the NRC took into account documented substance abuse recidivism rates

(highest within the first year following treatment, continuing at a somewhat lower rate for 3 years post-treatment, and decreasing again at 5 years) and stakeholder feedback.

Stakeholders have indicated that employers are generally reluctant to provide any information other than dates of employment, but that more recent employers are more likely to disclose adverse information than employers from previous years. Therefore, the NRC has determined that requiring every employer from the past 5 years to be contacted for all persons is both unnecessary and an unwarranted regulatory burden. Thus, for initial authorization, the employment check is to be conducted with every employer, regardless of the length of employment, for the past year, and with each employer by whom the individual claims to have been employed the longest in each calendar month for the previous 2 years. For authorization updates, the employment check is to be conducted with every employer, regardless of the length of employment, for the past year, and with each employer by whom the individual claims to have been employed the longest in each calendar month for the remaining time since authorization was terminated. For authorization reinstatements, the employment check is to be conducted with each employer by whom the individual claims to have been employed the longest in each calendar month since authorization was terminated. For individuals who have had a substance abuse problem, however, §26.69 requires a suitable inquiry for the applicable period specified by §26.63, as well as obtaining any records that other licensees or other entities may have developed relating to any potentially disqualifying FFD information about the individual.

Industry Comment 12: Allow credit for prior licensee's suitable inquiry.

Response: Proposed §26.63(b) would permit licensees to rely upon suitable inquiry information that was gathered by other licensees and entities. However, for all applicants for authorization, the suitable inquiry would be more thorough than previous industry practices, in

order to increase the likelihood that PDFFDI would be identified, if it existed, and to provide high assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse. For individuals who have established a recent, favorable work history within the industry, as demonstrated by having held authorization that was terminated favorably within the past 3 three years, the period of time addressed in the suitable inquiry would be reduced from the past 5 five years in every case, to the past 3 three years or less, depending upon how recently the applicant held authorization. If PDFFDI within the past 5 five years is identified regarding an applicant and the information had not been addressed and favorably resolved by a previous licensee or other entity, the suitable inquiry requirements would be more extensive, as described in proposed §26.69.

Industry Comment 13: Allow credit for prior licensee's medical determination of fitness.

Response: The NRC has clarified the qualification requirements for the medical personnel who may conduct a determination of fitness and believe that these clarifications will provide greater consistency in the determinations made across licensees. Therefore, a requirement for each new licensee to perform another determination of fitness for authorization reinstatements (authorization interrupted for 365 days or less) and authorization updates (authorization interrupted for >365 days to <3 years) when no new PDFFDI has been identified would be unnecessary.

Industry Comment 14: Requirements for FFD should be consistent with access authorization requirements.

Response: The provisions of the proposed rule are consistent with current access authorization requirements, including those in the recent access authorization Order, which the Commission issued to nuclear power reactor licensees on January 7, 2003.

Industry Comment 15: Medical determination of fitness for all individuals with a history of substance abuse creates an unnecessary burden.

Response: The proposed rule would add §26.189(b)–(d) to clarify the NRC's intent with regard to the circumstances in which a determination of fitness is required. Permitting licensees to accept the results of a determination of fitness conducted by a previous licensee, when no new PDFFDI has been identified, reduces the unnecessary burden that stakeholders referenced. However, a determination of fitness would continue to be required before an individual is granted authorization to perform activities within the scope of this part when PDFFDI is identified and has not been previously evaluated by another licensee.

Industry Comment 16: Rule does not allow shared audits of HHS-certified laboratories.

Response: The NRC believes that a requirement for independent audits by all licensees who rely on a laboratory is a redundant and unnecessary requirement. The proposed rule would specify requirements for sharing audits in proposed §26.41(g). This paragraph would state that licensees may jointly conduct audits, or accept audits of C/Vs and HHS-certified laboratories that were conducted by other licensees or entities subject to this part, when the services provided to the sharing licensees or entities by the C/Vs and HHS-certified laboratories are the same. Nonetheless, each sharing licensee is responsible for ensuring the correction of any deficiencies identified in audit results.

B. Key Stakeholder Comments not Incorporated into Proposed Rule and Responses

The headings below provide a listing of the significant comments received, but not incorporated, for each subpart in the proposed rule. The comments were received from

stakeholders during development of this proposed rule. Following each comment is a response detailing why the comment was not incorporated into the proposed rule.

Subpart A Administrative Provisions

There are no significant comments that were not incorporated into the proposed rule text.

Subpart B Program Elements

Comment 1 (NEI): The Medical Review Officer should not be included in the random testing program.

Response: Although current Section 2.3 [Preventing subversion of testing] in Appendix A to Part 26 requires licensees to carefully select and monitor individuals who are responsible for administering the drug and alcohol testing program based upon the highest standards of honesty and integrity, some licensees' testing programs did not include all of the FFD program personnel (including MROs) who the NRC originally intended to be subject to testing. The proposed change would be made to clarify the NRC's original intent because the actions of these individuals have an ongoing effect on public health and safety as a result of their responsibility to ensure that the FFD program is effective. In addition, these persons' actions affect the confidence that the public, management, and individuals who are subject to testing have in the integrity of the program and the accuracy and reliability of test results. Individuals who are involved in the day-to-day operations of an FFD program are in a position to permit substance abusers to remain undetected. For example, MROs could inadvertently commit errors when reviewing test results as a result of being impaired from drug or alcohol

abuse or because of motives associated with maintaining an MRO's substance abuse or empathy with an abuser. Furthermore, 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 specimen collectors to the testing pool after investigating an allegation and determining that two collectors were substance abusers. In another instance, a contracted MRO who was not in the testing pool was reported to be an alcoholic and an abuser of prescription drugs. Some MROs who provided their services to other Federally regulated industries were identified as substance abusers. Therefore, the proposed rule provision would fulfill the NRC's original objective and require licensees and other entities to extend their programs to include FFD personnel who (1) can link test results with the individual who was tested before an FFD policy violation determination is made, including, but not limited to the MRO; (2) make determinations of fitness; (3) make authorization decisions; (4) are involved in selecting or notifying individuals for testing; or (5) are involved in the collection or on-site testing of specimens.

Comment 2 (NEI): The FFD training requirements are too detailed, particularly the requirement for the FFD exam to be a separate exam, and for each knowledge and ability (KA) to be covered on each test.

Response: The proposed rule would require that individuals who are subject to the FFD program demonstrate attainment of the specified KAs by passing a comprehensive examination. This new requirement would be added because there have been several instances since Part 26 was first promulgated in which individuals were able to overturn determinations that they had violated a licensee's FFD policy on the basis that they had not understood the information they received during FFD training and so could not be expected to comply with the requirements of the policy. Therefore, the proposed rule would require

individuals to demonstrate their attainment of the knowledge and abilities to ensure that the FFD training has been effective. There would also be a requirement for the examination to include a comprehensive random sampling of all KAs with questions to test each KA, including at least one question for each KA, and establish a minimum passing score of 80 percent. These requirements would be modeled on other required training programs that have been successful in ensuring that examinations are valid and individuals have achieved an adequate understanding of the subject matter.

Comment 3 (Quest Diagnostics): Unannounced audits of HHS laboratories by the licensee, other entity, or NRC inspectors at any time is unreasonable given the other inspections, client tours, scheduled department meetings, and off-site requirements for testimony that are required of laboratories and their staff. The audits should also not be more than 48 hours in duration, and original documents or copies should not be allowed to be removed from the laboratory.

Response: The proposed rule would permit audits to be unannounced to enhance the effectiveness of the audit process should unannounced audits appear to be necessary. For example, a licensee or other entity may receive allegations that a laboratory is falsifying records or that laboratory employees are using drugs, and the licensee or other entity may determine that an unannounced audit would provide the most effective means to investigate such allegations. The proposed rule would ensure that the licensee's or other entity's contract with the lab would permit the unannounced audit as well as access to any information necessary to conduct the audit.

The NRC has also not proposed limits on the duration of such audits, as time limits may decrease the effectiveness and integrity of the audit process. Licensees or other entities may

determine they require more lengthy audits to effectively cover all intended areas, or to assess deficiencies.

The NRC has incorporated a provision to permit an HHS-certified laboratory to reasonably limit the use and dissemination of any documents copied or taken away by the licensee's or other entity's auditors in order to ensure the protection of proprietary information and donors' privacy. However, the NRC does not believe auditors should be restricted from copying or taking away documents that do not meet the above criteria, because doing so would decrease the efficiency and effectiveness of audits.

Subpart C Granting and Maintaining Authorization

Comment 1 (NEI): The process for granting authorization for individuals whose prior authorization was terminated unfavorably should be an initial.

Response: The proposed rule would require licensees to follow the proposed provisions in §26.69 for individuals whose prior authorization was terminated unfavorably due to an FFD concern. Licensees would not be permitted to use the proposed process for granting initial authorization for those individuals for several reasons. First, if an individual was terminated for a first positive drug or alcohol test result, and if it has been any period less than 3 years since that individual was terminated, then it would be unnecessary to require licensees and other entities to perform a suitable inquiry of the entire past 3 years (which would be required for an initial authorization). In those cases, proposed §26.69 would require licensees or other entities to perform a suitable inquiry for the period since the individual's authorization was terminated. Second, if an individual has had his or her authorization denied for 5 years, the suitable inquiry should be performed for the entire past 5 years (as required in proposed §26.69). The proposed process for granting initial authorization would only require a suitable

inquiry for the past 3 years, and the NRC believes that would not be appropriate in these situations. If an individual's prior authorization was terminated unfavorably for reasons that are unrelated to an FFD concern, the licensee would implement the relevant requirements in the access authorization Orders, which the Commission issued to nuclear power reactor licensees on January 7, 2003.

Comment 2 (NEI): There should not be any additional drug and alcohol testing for applicants for reinstatement of authorization whose last period of authorization ended between 6 and 30 days ago.

Response: The proposed rule would require licensees and other entities to subject applicants whose authorization has been interrupted for 6–30 days to the possibility of being selected for pre-access testing at a probability of approximately 4 percent. This probability approximates the likelihood that individuals who are subject to random testing at the 50 percent annual testing rate would be selected for testing at some point within a 30-day period. For applicants selected for such testing, the licensee or other entity would complete an alcohol test and collect a specimen for drug testing before reinstating the individual's authorization. The provision would enhance the deterrent effect of pre-access testing for individuals who have had a very short break in authorization, without imposing the regulatory burden of requiring that every individual be tested.

This is one of many changes to Subpart C that are being proposed to emphasize the NRC's intent that FFD programs provide "high," rather than "reasonable," assurance that persons who are subject to this part are trustworthy and reliable as demonstrated by the avoidance of substance abuse and the adverse behaviors that accompany it. To reduce the risk of an insider threat, maintain public health and safety, and provide for the common defense and security in the post-September 11, 2001, threat environment; the NRC has placed an

increased emphasis on the trustworthiness and reliability of individuals who have access to certain types of sensitive information, certain types of radiological materials, and protected areas in nuclear power plants — the same individuals who would be subject to the proposed rule. Because these individuals have unimpeded access to sensitive information and safety equipment and systems, their trustworthiness and reliability are essential. Pre-access testing is one important aspect of FFD programs designed to deter and detect substance abuse, which presents an unacceptable risk to public health and safety and the common defense and security in several ways.

First, substance abuse increases the likelihood that such individuals may pose an insider threat by increasing an individual's vulnerability to coercion. Under 10 CFR 73.1, a passive insider is defined as an individual who obtains or attempts to obtain safeguards or other relevant information, such as a nuclear power plant's physical configuration and design, and who does not have a functional or operational need to know such information. Section 73.1 defines an active insider as a knowledgeable individual who, while within the protected area of a nuclear power plant in an unescorted status, takes direct action to facilitate entrance and exit, disable alarms and communications, and/or participates in a violent attack. An individual who uses illegal drugs may be coerced into cooperating, actively or passively, with a terrorist in an attempt to commit radiological sabotage if, for example, the terrorist were to threaten the individual with revealing his or her illegal drug use or was somehow able to withhold drugs from an individual who is addicted.

Second, an individual's judgement and self-control are impaired while an individual is abusing drugs or alcohol. When an individual is intoxicated from abusing any of the substances for which testing is conducted under Part 26, including alcohol, the individual is more likely to

inadvertently reveal sensitive information that terrorists could use in a radiological sabotage attempt than when he or she is not intoxicated.

Third, the use of illegal drugs establishes that an individual is willing to disobey the law, thus indicating that the individual will disregard other rules and regulations. The use of illegal drugs raises questions about the individual's trustworthiness and reliability in terms of scrupulously following the regulations, procedures, and other requirements, such as safeguards requirements, that ensure the protection of public health and safety.

Many provisions of the current rule provide means to identify and reduce the risks posed by any individuals whose substance abuse casts doubt on their trustworthiness and reliability. In combination with other measures the NRC has taken since September 11, 2001, the proposed requirement that individuals who have had a break in authorization of between 6–30 days must be subject to one-time selection for pre-access testing would provide further assurance that those individuals are trustworthy and reliable. The NRC believes that implementation of this provision and other provisions in the proposed rule, in addition to the other, related measures the Agency has taken in the post-September 11, 2001, threat environment, would provide high assurance that individuals who are subject to the rule are trustworthy and reliable.

Subpart D Management Actions and Sanctions to be Imposed

There are no significant comments that were not incorporated into the proposed rule text.

Subpart E Collecting Specimens for Testing

There are no significant comments that were not incorporated into the proposed rule text.

Subpart F Licensee Testing Facilities

Comment 1 (NEI): Significant QA requirements have been added, which makes licensee testing facilities perform at the same level as an HHS-certified laboratory. This will result in licensees closing many of their licensee testing facilities.

Response: New requirements would be added for conducting initial urine specimen validity tests at licensee testing facilities. Specimen validity testing refers to testing conducted to identify attempts to tamper with a specimen. This includes adulteration, which means putting a substance into a specimen that is designed to mask or destroy the drug or drug metabolite that the specimen may contain or to adversely affect the assay reagent; substitution, which includes replacing a valid urine specimen with a drug-free specimen; and dilution, which includes intentionally diluting a urine specimen with another liquid to decrease the concentration of a drug below the cutoff concentration. When HHS published its Notice of Proposed Revisions (66 FR 43876; August 21, 2001) to the HHS Guidelines to establish requirements for specimen validity testing performed by HHS-certified laboratories, the HHS reported that the number of adulterated and substituted urine specimens has been increasing among the specimens tested under the Federal agency workplace drug testing program and the U.S. Department of Transportation (DOT) regulations (49 CFR part 40). Program experience gained since Part 26 was first promulgated has also indicated an increasing number of adulterated and substituted urine specimens. Although current Part 26 contains a number of requirements related to specimen validity, the methods available to tamper with specimens have become

more sophisticated since the rule was first published and therefore more sophisticated methods of detecting tampering are necessary. The proposed rule would incorporate new requirements for conducting specimen validity tests that are consistent with similar provisions contained in the most recent revision to the HHS Guidelines (69 FR 19643; April 13, 2004). These new requirements for specimen validity testing would be added to strengthen FFD programs by improving the ability to detect specimens that are adulterated, substituted, or diluted.

The requirements for specimen validity testing are proposed to identify individuals who are willing to attempt to subvert the testing process, and so may be willing to subvert other rules and regulations that are important for public health and safety and the common defense and security. Detecting specimen tampering is necessary to identify individuals who may attempt to hide drug abuse, because attempts to tamper with a specimen provide clear evidence that the individual is not trustworthy and reliable.

The proposed rule would permit licensees to conduct drug and validity screening tests, and to grant authorization to individuals whose specimens yield negative test results. If the NRC were not to include quality assurance and training requirements in conjunction with such tests, but still permit licensees to grant authorization on the basis of the tests, then the NRC would not have high assurance that only individuals who are trustworthy and reliable are granted authorization. Therefore, the NRC has included such provisions in this proposed rule.

Comment 2 (NEI): Licensees should be permitted 3 business days to send Bottle B of a split specimen to the HHS lab for testing, following a request from the donor.

Response: The proposed rule would extend the time period provided to the licensee to send Bottle B to the HHS-certified laboratory. The current rule requires that the specimen must be sent the same day as the donor request. The proposed rule would allow 1 business day to send the specimen. The proposed rule would not allow 3 days, as requested by NEI, because

the proposed rule would also require licensees to administratively withdraw the individual's authorization at the time Bottle A is confirmed non-negative. The NRC believes that permitting up to 3 days would pose an unnecessary burden on the individual, especially because some licensees temporarily remove pay until the Bottle B test is complete. The NRC also believes that 1 business day would provide sufficient time for the licensee to locate Bottle B, prepare it for shipping, and deliver it to the courier.

Subpart G Laboratories Certified by the Department of Health and Human Services

Comment 1 (Quest Diagnostics): If an individual who is the subject of a drug test requests in writing to have access to the laboratory's records related to his or her drug test, the records released should be limited to the laboratory test report and data package, and not include the results of any relevant certification, review, or revocation-of-certification proceedings. Blanket releases by the employee to third parties should be prohibited.

Response: The proposed rule would permit an individual to have access to laboratory records, as well as a third party such as an attorney to whom the employee has released the information. The records that an employee may request include laboratory records beyond the individual's drug test results because other records may be relevant to litigation. For instance, if a laboratory audit subsequent to the individual's test uncovers improper testing that may be relevant to the individual's test, that information may be useful in litigation. The NRC sees no justification for withholding such information from an individual or an authorized third party, and believes access to such information to be consistent with protection of the individual's rights and with due process. The provision is also consistent with HHS guidelines and Sec. 503 of Pub. L. 100-71 for Federal workplace drug testing.

Comment 2 (Quest Diagnostics): Cutoff levels should be consistent with new HHS proposed Guidelines.

Response: The NRC typically considers HHS provisions for inclusion into a Part 26 proposed rule following the issuance of final HHS Guidelines. This is to minimize the possibility that a Part 26 proposed rule must be re-proposed due to changes in the HHS Guidelines between their proposed and final forms, and to ensure proper stakeholder interaction in the technical basis development stage, followed by public review and comment of the Part 26 proposed provisions. The NRC will consider the proposed HHS Guidelines for inclusion into the technical basis development for a future Part 26 rulemaking once they have been finalized by HHS.

Subpart H Determining Fitness-for-Duty Policy Violations and Determining Fitness

Comment 1 (NEI): The MRO has too much independent responsibility, given that the licensee is responsible for the program. The MRO is part of the licensee program and should be accountable within the program, not independent of the program.

Response: The proposed rule would require that MRO and MRO staff duties must be independent from any other activity or interest of the licensee or other entity. Although the NRC is unaware of any instances in which the MRO function has been compromised in Part 26 programs, the experience of other Federal agencies has indicated that clear limits on independence and who may direct MRO staff activities are advisable. Further, in contrast to other Federal agencies' regulations, current Part 26 permits employees of licensees and other entities to perform MRO staff activities for MROs who work off site and are not physically present to supervise the staff, which may provide greater opportunities for inadvertent compromise of the independence of the MRO function than situations in which the MRO and his

or her staff are physically co-located. Independence of the MRO function from the licensee or other entity is necessary to ensure that MROs are impartial gatekeepers for the accuracy and integrity of the drug testing process and also to ensure the confidentiality of medical information.

Comment 2 (NEI): The SAE requirements for qualification are excessive.

Response: Detailed requirements regarding the qualifications and responsibilities of the SAE are necessary to ensure consistency among FFD programs. This is because under the proposed rule, FFD programs would be permitted to accept determinations of fitness and treatment plans from other Part 26 programs, if an individual who has had a substance abuse problem will be granted authorization by another licensee or entity. In addition, detailed requirements regarding the qualifications and responsibilities of the SAE are necessary because of the key role the SAE would play in assuring the public health and safety and common defense and security when making a determination of fitness. The SAE role is not defined in the current rule. Therefore, many of the provisions in the proposed subpart would be adapted from related DOT requirements regarding the "substance abuse professional" [49 CFR Part 40, Subpart O; 65 FR 41944; August 9, 2001]. Additionally, the NRC has received feedback on implementation of the current rule that some MROs do not feel qualified to make decisions on substance abuse treatment and rehabilitation. Under the proposed rule, the critical tasks of assessing the presence of a substance abuse disorder, providing input to authorization decisions, and developing treatment plans would be reserved for professionals who have met the specific training, clinical experience, and knowledge requirements for an SAE.

Subpart I Managing Fatigue

Subpart I would establish clear and enforceable requirements concerning the management of fatigue at nuclear power plants. Many stakeholders took an interest in, and commented on Subpart I through the public meetings, including IBEW, UCS, the Nuclear Energy Institute (NEI), the Professional Reactor Operator Society (PROS), industry representatives, and Barry Quigley, the petitioner, among others. Because of the level of interest and commenting on Subpart I, in comparison to the other subparts, several key comments that were not incorporated, and their responses, are provided below for each of the stakeholders listed above.

Comment 1 (IBEW): Individuals allowed to perform fatigue assessments should be trained to a higher level than others.

Response: The NRC is proposing to train individuals and supervisors to the same level because fatigue management is a shared responsibility. The proposed level of training would provide the knowledge needed to perform a fatigue assessment, including providing an understanding of the indications and effects of fatigue, and the appropriate use of fatigue countermeasures. This ensures that those individuals who may undergo a fatigue assessment have been trained to understand the process to which they will be subject and what the assessor will be looking for, in addition to being able to recognize the signs of fatigue in their coworkers. Because the training on what to expect from a fatigue assessment is not substantially different from how to conduct one, for simplicity of implementation, all workers would be trained to the same level. In addition, the proposed revisions to drug and alcohol testing provisions would revise that training such that all workers are required to be trained to the same level. The fatigue training would therefore be consistent with those provisions as well.

Comment 2 (Patrick Shaffer, Southern California Edison): The 48 hour/week group average limit is not high enough for groups other than security force personnel that would be subject to the proposed work hour controls. A 60 hour/week group average limit would be preferable.

Response: Answered in the response to Comment 4, below.

Comment 3 (Barry Quigley, petitioner): The group average limit should not be increased above a 48 hour/week limit.

Response: Answered in the response to Comment 4, below.

Comment 4 (UCS): The proposed rule would permit the entire affected workforce to work 53-hour weeks [including shift turnover time], which erodes fatigue protection from the 40-hour weeks recommended in NRC's Policy on Worker Fatigue.

Response: The objectives of the 48-hour group limit during normal plant operations are to ensure that the amount of overtime typically worked by individuals does not adversely affect their abilities to safely and competently perform their duties, to define an enforceable upper limit to the nominal 40-hour work-week policy in GL 82-12, and to permit licensees to manage overtime in a manner that reflects the differing desires and capabilities of individuals with respect to work hours. A more detailed discussion of the basis for requiring a 48 hour/week group average limit is provided in Section VI with respect to proposed §26.199(f), and is also summarized below.

A 40-hour work-week during normal operations is a key objective of the NRC's Policy on Worker Fatigue. The policy is intended to ensure that there are enough operating personnel to "maintain adequate shift coverage without routine heavy use of overtime." However, the policy, and the 40-hour work-week objective, are not enforceable.

Routine overtime can cause cumulative fatigue, which degrades the abilities of workers to safely and competently perform their duties. The proposed collective work hour controls, including the 48-hour per week group limit during normal plant operations, would address cumulative fatigue by establishing more readily enforceable requirements for the long-term control of work hours, including the limited use of overtime for occasional short-term exigent circumstances (e.g., equipment failure, personnel illness or attrition). The 48-hour group limit would reduce the potential for cumulative fatigue by preventing excessive use of the maximum allowable individual limits during normal plant operations. The current regulatory framework does not contain enforceable requirements to prevent such practices. In addition, by limiting work hours during normal conditions, individuals would be better rested and less susceptible to cumulative fatigue from the long work hours that are common during plant and security system outages. Further, it would provide reasonable assurance that individuals will be better rested prior to an emergency or increased threat condition.

The proposed requirement would limit groups of individuals to a 48-hour average, permitting 20 percent overtime in excess of the nominal 40-hour work week. Consideration of several types and sources of information led to the decision to establish a group average limit of 48 hours for normal plant conditions. These included past recommendations from experts and expert panels on work scheduling and maintaining worker alertness in the nuclear industry, surveys of nuclear power plant workers on their desire and ability to work overtime, data and industry practices on the amount of overtime worked by security personnel, and requirements and practices in other industries. A detailed description of the sources of information is included in Section VI with respect to proposed §26.199(f).

Comment 5 (NEI): A 56-day outage exclusion from the 48-hour group average work hour limits is insufficient.

Response: Answered in the response to Comment 7, below.

Comment 6 (UCS): The work hour limits should not be turned off based on an unrelated artificial construct, such as outage duration(s) and national security levels. Instead, the rule should state the work hour limits for short and long terms.

Response: Answered in the response to Comment 7, below.

Comment 7 (Barry Quigley, petitioner): Outages should not be excluded from the group work hour average limits.

Response: The collective work hour controls address the long-term control of work hours, including the limited use of overtime for occasional short-term exigent circumstances (e.g., equipment failure, personnel illness or attrition). However, the NRC recognizes the need to address separately the control of work hours during outages because of the unique staffing and workload demands of this plant state. Accordingly, the proposed rule would permit a limited exclusion period for plant outages from the collective work hour controls.

The NRC considered several factors, including current policy, the bases for the policy, and lessons learned from the policy implementation in developing a provision to permit a limited exclusion period for plant outages from the collective work hour controls. The NRC's Policy on Worker Fatigue provides guidelines for controlling work hours, "on a temporary basis," during periods requiring substantial overtime. The policy reflects the NRC's recognition that outages are unique, relatively short-term, plant circumstances involving levels of activity that are substantially higher than most non-outage operating periods. The policy also reflects the NRC's understanding that although individuals are capable of working with limited rest without degradation of performance for short periods of time, research has shown that the ability to sustain performance without adequate rest is clearly limited. However, the NRC has never defined the term "temporary basis" as used in the policy. As a consequence, licensees have

used the guidelines to control working hours for conditions ranging from a few days to more than a year. Industry experience with conditions such as sustained plant shutdowns and the increased work hours of security personnel following the terrorist attacks of September 11, 2001, have indicated the need to establish clear and more readily enforceable requirements that would limit the sustained use of extended work hours.

The NRC considered several factors in setting the exclusion period for plant outages at 8 weeks. First, by the end of 8 weeks of work at the limits permitted, individuals will have worked 540 hours, including 200 hours of overtime. This is 50 percent of the hours that surveys of nuclear plant workers have indicated are acceptable on an annual basis. Second, by the end of 8 weeks of work at the limits permitted, individuals will have missed as many as 17 normally scheduled days off, a reduction of 60 percent in the time available to recover and prevent cumulative fatigue. In addition, with each passing week of an outage, individuals have worked an increasing number of normally scheduled days off. The ability to defer daily living obligations becomes increasingly difficult, causing increased pressure to reduce sleep time in order to meet demands of both work and daily life, and increased potential for cumulative fatigue.

In addition to considering the potential for cumulative fatigue, the NRC considered current industry data concerning the duration of plant outages. The average refueling outage duration, as indicated by outage data from 2000–2002 in the Information System on Occupational Exposure database (ADAMS Accession No. ML050190016), is approximately 39 days. Eighty-nine percent were less than 8 weeks in duration. In reviewing the frequency of outages, by duration, the NRC found that it would be necessary to increase the exclusion period substantially to include a marginal number of additional outages. The NRC believes that such an increase in the exclusion period would substantively increase the potential for

cumulative fatigue and fatigue-related personnel errors. By contrast, decreasing the exclusion period to less than 8 weeks would rapidly increase the number of outages that would, in part, be subject to the collective work hour controls, potentially increasing the duration and cost of those outages. The NRC acknowledges that decreasing the exclusion period by 1 or 2 weeks could decrease the potential for cumulative fatigue, but the magnitude of the decrease would be difficult to quantify and the benefit would not likely justify the costs.

The NRC believes that an exclusion of the first 8 weeks of an outage is consistent with the objective of ensuring that licensees provide adequate shift coverage without routine heavy use of overtime. The exclusion period would be limited to plant outages, which occur regularly, but with limited frequency. In addition, the duration of the exclusion period would be limited to 8 weeks, thereby providing reasonable assurance that workers would be able to safely and competently perform their duties, and not be impaired from cumulative fatigue.

The NRC further considers that the exclusion of security system outages and increased threat conditions is appropriate. In these conditions, maintaining plant security is of the utmost importance. It is specifically during these conditions that the NRC believes that the benefits to the common defense and security of augmenting on-shift security staffing during those conditions outweigh the potential risk from increased fatigue for those time periods.

Comment 8 (PROS and UCS): Turnover time is excluded from the work hour limit calculations, but there is no maximum allowed turnover time. This could lead to excessive time allocated to turnovers, and therefore hours worked.

Response: Although the NRC believes it is necessary and justified to limit the number of hours worked by certain individuals to ensure public health and safety and the common defense and security, the NRC also believes shift turnovers contribute significantly to safety and security. If the proposed rule included shift turnover in the work hour calculations, licensees

may have an incentive to limit turnover time, which could have a negative impact on safety and security. The NRC believes the importance of an accurate and thorough turnover should not be undermined through the imposition of work hour restrictions related to turnover.

The NRC shares the commenters' concern that excessive time allocated to turnovers could result in excessive hours worked. Therefore, proposed §26.199(b)(1)(i) would specify the types of activities that would and would not be considered shift turnover activities under the proposed rule. For example, the proposed paragraph would define shift turnover activities as only those activities that are necessary to safely transfer information and responsibilities between two or more individuals between shifts. By contrast, the early arrival of an individual for meetings, training, or pre-shift briefings for special evolutions would not be considered shift turnover time. The NRC believes that the proposed specifications for shift turnover activities would be sufficient to ensure that excluding shift turnover time from work hours calculations, combination with the other requirements for fatigue management in the proposed rule, would be sufficient to prevent individuals from working excessive hours.

Comment 9 (UCS): The formal determination that a waiver of the individual work hour limits and break requirements "is necessary to mitigate or prevent a condition adverse to safety," or to "maintain the security of the facility," is hardly a robust barrier when one considers all the safety-challenged things that have been changed at nuclear power plants under the far more restrictive provisions of 10 CFR 50.59.

Response: The provisions of 10 CFR 50.59 do permit many minor changes to be made at nuclear reactors because the safety criteria are stated in the negative. In other words, a licensee is permitted to make changes that do not have an adverse impact. In contrast, the proposed waiver criteria would work in the positive. Minor safety issues would not constitute a valid justification for a waiver of the individual limits or break requirements because the criteria

are stated in the positive. Only work that "is necessary to mitigate or prevent a condition adverse to safety," or to "maintain the security of the facility," would meet the criteria. This is consistent with the NRC's intent that waivers be approved only in very limited circumstances. The NRC believes granting of waivers in these extreme cases is justified and in the public interest because the gain in safety or security from the work being completed in an unimpeded manner would offset the potential reduction in safety or security from worker fatigue.

Comment 10 (NEI): Waivers should be allowed for pressing economic concerns.

Response: The criteria for granting waivers from individual short-term work hour limits and break requirements were strengthened from current plant technical specification requirements to permit the granting of waivers only for conditions adverse to safety or security. Industry data have shown significant over-use of waivers, mostly for commercial reasons, as is detailed in the Regulatory and Backfit Analysis prepared for this proposed rule. The NRC believes the individual short-term work hour limits and break requirements should only be waived in unique circumstances, on a very infrequent basis, and only when necessary for safety or security. Permitting waivers for economic reasons would increase the potential risk to public health and safety and the common defense and security from worker fatigue without an off-setting gain to safety or security. As described in this section with respect to the individual limits in proposed §26.199(d)(2) and (3), the potential for worker fatigue in conditions that would require a waiver is substantial (Baker, et al., 1994; Dawson and Reid, 1997; Stephens, 1995; Strohl, 1999). As a consequence, the NRC does not believe that licensees can reasonably justify the performance of risk significant functions at work hours in excess of the proposed limits on the basis that the action would not constitute an adverse impact on safety or security. During the public meetings described in Section V, industry stakeholders proposed that a senior site manager have the authority to grant waivers if the manager "determines that the deviation

will not have an adverse impact on safety or security." The NRC does not believe that the criterion proposed by industry stakeholders is appropriate for several reasons. The work hour limits of proposed §26.199(d) would apply only to personnel performing risk significant functions. If an activity is not risk significant, it is not subject to the work hour controls and therefore a waiver is unnecessary. The proposed waiver criteria, therefore, do not impose unnecessary restrictions in such circumstances. Further, the NRC does not believe the proposed work hour limits and minimum break requirements are unnecessarily conservative. The criterion proposed by industry representatives is also highly subjective. In light of concerns regarding industry's past use of deviations that the NRC documented in SECY-01-0113, the use of a subjective criterion would not be an effective regulatory approach to mitigating the past over-use of waivers by certain licensees.

Comment 11 (NEI): There should not be a reporting requirement for the number of waivers granted.

Response: As detailed in the Regulatory and Backfit Analysis, the industry has, and continues to, grant excessive numbers of waivers each year. Although the proposed provisions are expected to greatly limit the number of waivers licensees can grant each year, the NRC believes it is necessary and justified to monitor the number of waivers granted, along with other indicators of FFD program performance that are proposed to be monitored, to ensure the rule is implemented as intended and that the fatigue portions of FFD programs are effective. The NRC has weighed the burden introduced in the proposed reporting requirement with the burden that would otherwise be required of NRC staff and inspectors to perform such monitoring and has determined the burden is justified. In that determination, the NRC has also considered that a yearly FFD program performance report is currently required for the drug and alcohol testing

program, and the additional reporting for the fatigue programs would merely add to the report, not create a new one.

Comment 12 (NEI): The fire brigade should not be subject to Subpart I requirements.

Response: The proposed work hour limits would be applicable only to those members of the fire brigade who are responsible for understanding the effects of fire and fire suppressants on safe shutdown capability for the reactor. This knowledge enables them to provide the control room operators and fire brigade leader with information that is critical to implementing a fire mitigation strategy that maintains safe shutdown capability. For application of the collective work hour controls specified in §26.199(f), these fire brigade members could be averaged with another work group (e.g., operations) for those individuals who perform the duties of both groups. Attachment 1 to SECY-99-140, Recommendation for Reactor Fire Protection Inspections, dated May 20, 1999, states that "based on IPEEE results, fire events are important contributors to the reported core damage frequency (CDF) for a majority of plants. The reported CDF contribution from fire events can, in some cases, approach (or even exceed) that from internal events." Fire brigade members must retain the cognitive ability to be able to think and determine the best way to suppress a fire to prevent additional damage to safety-related equipment, evaluate equipment affected by a fire to report to control room operators concerning equipment availability, make decisions concerning smoke ventilation to prevent the fire effects from affecting other plant operations, and coordinate all activities with control room operators.

Fatigue can substantially degrade a worker's decision-making and communication abilities, cause a worker to take more risks, and cause a worker to maintain faulty diagnoses throughout an event, as detailed in Section IV. D. These abilities are key to the duties of the fire brigade members who are responsible for understanding the effects of fire and fire

suppressants on safe shutdown capability for the reactor. Degradations of these abilities could have significant consequences on the outcome of an event involving a fire. For instance, a fatigued worker could incorrectly decide to vent smoke or toxic gas to an area required for alternate shutdown, which could prevent or impair access to equipment needed for safe shutdown of the plant. In addition, a fatigued worker could incorrectly apply the wrong fire suppressant, which could affect additional equipment in the plant. Further, impaired decision-making could lead a worker to improperly control flooding, which could impact other needed equipment, or could incorrectly determine whether an area contains critical equipment and improperly apply a suppressant in that area. Impaired communications could also lead to incomplete disclosure of information to licensed operators in the control room, which could adversely impact the decision-making of those operators. If information known to the impaired worker is not properly communicated, operators may not initiate appropriate actions to mitigate the fire effects, or effects of suppressant activities, on critical equipment. As a consequence, ensuring that the ability of fire brigade members to safely and competently assess the effects of a fire and fire suppressants on safe shutdown capability is essential to the overall success of the fire mitigation strategy and the protection of public health and safety.

Further, the NRC periodically grants exemptions from requirements in 10 CFR Part 50, Appendix R [Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979] based on protection of the levels of defense in depth listed in Section II(A) of Appendix R to Part 50, which are “To prevent fires from starting; To detect rapidly, control, and extinguish promptly those fires that do occur; To provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by the fire suppression activities will not prevent the safe shutdown of the plant.” Granting these exemptions is often predicated on effective manual suppression of a fire by the fire brigade.

Comment 13 (NEI): There should not be requirements for a 48-hour break every 14 days and a 24-hour break every 7 days.

Response: The NRC believes the proposed 24- and 48-hour break requirements are necessary to reduce the effects of acute and cumulative fatigue. A more detailed discussion of the basis for requiring the 24- and 48-hour breaks is provided in Section VI with respect to proposed §26.199(d)(2), and is also summarized below.

Acute fatigue results from excessive cognitive work and especially from significant amounts of missed sleep. It is readily relieved by obtaining adequate rest and sleep. Cumulative fatigue results from individuals receiving inadequate sleep for successive days. As fatigue increases, performance is increasingly impaired, shows greater variability, and manifests itself in the form of errors of omission and commission. Research has shown that lack of adequate days off and extended workdays can result in cumulative sleep debt and performance impairment. This research, as well as other considerations, is discussed in detail in Section VI with respect to proposed §26.199(d)(2).

Additionally, the NRC considers the 24- and 48-hour breaks to be a key component of fatigue mitigation for the transient workforce. Contract and other temporary personnel move from one plant outage to another within a region or nationally. During most portions of an outage, these personnel would be subject only to the proposed individual limits and break requirements. The break requirements, in conjunction with the consideration that such temporary workers likely have periodic seasonal breaks between outages, provides reasonable assurance that they will not be impaired from either acute or cumulative fatigue.

Comment 14 (PROS): Utilities should not be allowed to work licensed operators up to 16 hours straight, they should be limited to 12 hours.

Response: Although proposed Subpart I would not prohibit the use of 16-hour shifts, the proposed rule includes requirements that collectively address this concern. The proposed rule would include controls that would reduce the frequency of 16-hour shifts. These controls include proposed §26.199(d)(1)(ii), which would limit the maximum hours worked in any 48-hour period to no more than 26 hours. This limit prohibits individuals from working 16-hour shifts on two consecutive days. Proposed §26.199(d)(2)(i) would require a minimum 10-hour break between work periods and provide workers with the opportunity for 7–8 hours of sleep. This requirement would create a substantial disincentive for using 16-hour shifts. Specifically, individuals who work 16-hour shifts would not be eligible to return to work at the beginning of the next normally available shift.

The NRC acknowledges that 16-hour shifts can substantially increase the probability for human error. Accordingly, the NRC believes that fatigue management must include limiting the use of 16-hour shifts to the extent practicable and applying effective behavioral observation and fatigue mitigation strategies when such conditions are unavoidable. The training requirements in the proposed rule would provide individuals and supervisors with the knowledge to make effective decisions regarding fatigue, which should result in the scheduling of fewer 16-hour shifts. The proposed rule would also require licensees to establish a process to be followed if an individual declares that he or she is not fit for duty, for any reason, including fatigue. The NRC would expect that individuals who believe that they are incapable of safely and competently completing a 16-hour shift would make an appropriate self-declaration.

Collectively, the requirements of the proposed rule would be expected to: (1) substantially limit the frequency of 16-hour shifts, (2) provide assurance that, when such work hours are necessary, licensees have the knowledge and abilities to assess the potential for degraded performance and need for fatigue countermeasures, and (3) ensure workers have a

process for resolving concerns regarding fatigue from extended work hours. As a consequence, the NRC believes that the proposed requirements are appropriate for maintaining worker fitness for duty and, thereby, protecting public health and safety and the common defense and security.

Comment 15 (Barry Quigley, petitioner): The work hour controls in Subpart I should apply to all individuals performing risk-significant work, such as engineers and all fire brigade personnel.

Response: The proposed requirements would cover all personnel who perform duties within one of the following job duty groups: (1) operating or on-site directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health and safety; (2) performing maintenance or on-site directing of the maintenance of structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety; (3) performing Health Physics or Chemistry duties required as a member of the on-site emergency response organization minimum shift complement; (4) performing the duties of a Fire Brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability; and (5) performing security duties as an armed security force officer, alarm station operator, response team leader, or watchperson (hereinafter referred to as security personnel).

Engineers who direct, on-site, the maintenance or operations of risk-significant structures, systems, and components would be subject to group work hour controls. The NRC believes those engineers who perform such duties should be subject to group work hour controls. A few examples of such direction would be engineers who act as test directors in the control room, engineers who provide direction to maintenance crews (such as during an outage), engineers who provide technical direction and guidance for reactivity manipulations

and power changes, as well as many other similar engineering functions. However, the NRC does not believe that engineers, or other individuals, who do not perform those duties should be subject to group work hour controls. Many engineers do not direct maintenance or operations, and many others do not work with risk-significant plant systems, structures, or components. A few examples of engineering activities that the NRC does not consider direction include design modifications, assisting in procedure changes (including writing and modifying procedures for covered work groups such as operations), performing technical analyses, monitoring the performance of systems and recommend maintenance, as well as many other similar engineering functions.

The NRC is not proposing to require licensees and other entities to subject all engineers to work hour controls because many engineering tasks, such as modification design, are reviewed by managers, peer reviewers, and others before being implemented. The same is the case for routine performance monitoring. Any maintenance recommended by an engineer as a result of performance monitoring would typically be reviewed by managers or work planners in maintenance. Therefore, the NRC has reasonable assurance that errors committed by an engineer in these circumstances would be found and corrected through the normal plant review processes.

In the case of fire brigade personnel, the NRC is proposing that only those fire brigade personnel who are responsible for understanding the effects of fire and fire suppressants on safe shutdown capability would be subject to work hour controls. The NRC does not propose to include other members of the fire brigade because they are principally engaged in manual actions. These types of actions do not require substantial analysis and decision-making capability, and individuals engaged in manual actions would be expected to perform those actions without significant degradation from fatigue. Diagnosis and decision-making functions

are affected by fatigue to a much greater extent, and are collectively more critical to emergency response. For these reasons, the NRC proposes work hour controls on only the fire brigade members who are responsible for understanding the effects of fire and fire suppressants on safe shutdown capability.

Subpart J Recordkeeping and Reporting Requirements

There are no significant comments that were not incorporated into the proposed rule text.

Subpart K Inspections, Violations, and Penalties

There are no significant comments that were not incorporated into the proposed rule text.

VI. Section-by-Section Analysis of Substantive Changes

The proposed rule would be organized into eleven subparts that are comprised of related requirements, as follows:

Subpart A - Administrative Provisions

Subpart B - Program Elements

Subpart C - Granting and Maintaining Authorization

Subpart D - Management Actions and Sanctions to be Imposed

Subpart E - Collecting Specimens for Testing

Subpart F - Licensee Testing Facilities

Subpart G - Laboratories Certified by the Department of Health and Human Services

Subpart H - Determining Fitness-for-Duty Policy Violations and Determining Fitness

Subpart I - Managing Fatigue

Subpart J - Recordkeeping and Reporting Requirements

Subpart K - Inspections, Violations, and Penalties

A detailed cross-reference table between the current and proposed Part 26 provisions is included at the end of this notice.

Appendix A of the current rule would be deleted and the detailed requirements for conducting drug and alcohol testing that are contained in Appendix A to 10 CFR Part 26 would be moved to Subpart E [Collecting Specimens for Testing], Subpart F [Licensee Testing Facilities], and Subpart G [Laboratories Certified by the Department of Health and Human Services] of the proposed rule.

Subpart A – Administrative Provisions

Section 26.1 Purpose

Section 26.1 [Purpose] of the proposed rule would amend the language of the corresponding section of the current rule. The proposed paragraph would delete the term, “certain aspects,” as unnecessary. The proposed paragraph would add the term, “implementation,” to the phrase in the current rule which states, “for the establishment and

maintenance of ... fitness-for-duty programs," in order to convey more accurately that the proposed rule includes requirements for implementing FFD programs, in addition to requirements for establishing and maintaining such programs. The portion of current §26.1 that refers to the entities who are subject to the rule would be moved to proposed §26.3 [Scope] in order to consolidate this information in a more appropriate location.

Section 26.3 Scope

Proposed §26.3 [Scope] would renumber, reorganize, and amend current §26.2 [Scope]. In general, proposed §26.3 would retain the list of entities who are subject to the current rule and add other entities. However, the provisions in current §26.2 that specify the individuals whose job duties require them to be subject to the rule and exempt certain other individuals would be moved to a new section, proposed §26.25 [Individuals subject to the fitness-for-duty program]. The provisions that would be moved to proposed §26.25 include the second sentence of current §26.2(a), the first sentence of current §26.2(b), and the portion of the second sentence of current §26.2(d) that pertains to personnel. The NRC determined that separating into two different sections the requirements that address the entities who are subject to the rule and the requirements that address the individuals who must be subject to the rule would make the two sets of provisions easier to locate within the rule without compromising the intended meaning of these provisions.

Proposed §26.3(a) would add combined operating license holders to be consistent with the revised 10 CFR Part 52 licensing process for new reactors.

Proposed §26.3(b) would retain the requirement in the first sentence of current §26.2(a) that licensees who are authorized to possess or use formula quantities of SSNM or to transport

formula quantities of SSNM are subject to the regulations in this part. However, these licensees would not be subject to the requirements contained in proposed Subpart I [Managing Fatigue] for the reasons that will be discussed later in this document in relation to proposed §26.195 [Applicability].

Proposed §26.3(c) would retain the requirements of current §26.2(d) and add references to entities other than a corporation because there may be entities who are organized as firms, partnerships, limited liability companies, or associations who may also obtain a certificate or approved compliance plan under Part 76 and elect to engage in activities involving formula quantities of SSNM. The proposed paragraph would also add a cross-reference to proposed §26.25(a)(3), which specifies the individuals who are employed by or under contract to these entities who would be subject to Part 26. The entities in the proposed paragraph would not be subject to the requirements in proposed Subpart I [Managing Fatigue] for the reasons that will be discussed later in this document in relation to proposed §26.195 [Applicability].

Proposed §26.3(d) would retain the meaning of the portion of current §26.23(a)(1) that requires a contractor/vendor (C/V) FFD program to meet the standards of this part if licensees rely upon the C/V's FFD program to meet the requirements of this part, but amend some of the terminology used in the current rule. The proposed paragraph would add C/Vs to the list of entities who are subject to Part 26 in proposed §26.3 in order to more clearly convey that C/Vs may be directly subject to NRC inspection and enforcement actions than the current rule language implies. The current rule text presents the applicability of the rule's requirements to a C/V's FFD program in terms of the contractual relationship between a licensee and the C/V. For example, current §26.23(a)(1) states, "The contractor or vendor is responsible *to the licensee* [emphasis added] for adhering to the licensee's fitness-for-duty policy, or maintaining and adhering to an effective fitness-for-duty program; which meets the standards of this part."

This paragraph, and others in the current rule, could be interpreted as implying that a C/V is accountable to the licensee but not to the NRC, should significant weaknesses be identified in the C/V's FFD program upon which a licensee relies. However, this interpretation would be incorrect. Therefore, proposed §26.3(d) would include C/V FFD programs and program elements upon which licensees and other entities rely within this section to convey more accurately that C/Vs are directly accountable for meeting the applicable requirements of Part 26, rather than accountable only through their contractual relationships with the licensees and other entities who are subject to the rule. This clarification is also necessary to maintain the internal consistency of the proposed rule because some provisions of the proposed rule apply only to C/Vs, including, but not limited to proposed §26.217(g).

The phrases, "program elements" and "to the extent that licensees and other entities rely upon those C/V FFD programs or program elements to meet the requirements of this part," would be used in proposed §26.3(d) because C/Vs would need only meet the requirements of Part 26 for those FFD program elements upon which licensees and other entities rely to meet the requirements of the rule. For example, a C/V may choose to implement all of the program elements that are required for a full FFD program under the proposed rule except drug and alcohol testing. In this case, the proposed rule would not require the C/V to address drug and alcohol testing in the C/V's FFD policy, procedures, and training program; establish contracts with drug-testing laboratories; collect specimens for drug and alcohol testing; or meet any other requirements in the proposed rule that relate to conducting drug and alcohol testing. However, if a C/V chooses to conduct drug and alcohol testing under some or all of the conditions specified in proposed §26.31(c) [Conditions for testing], such as for-cause testing, and a licensee or other entity who is subject to Part 26 relies upon the results of the C/V's tests in determining whether to grant authorization to an individual (see proposed Subpart C [Granting

and Maintaining Authorization]), then the use of these two phrases in the proposed paragraph would be correctly interpreted as meaning that the C/V's drug and alcohol testing program element must meet the proposed rule's requirements related to drug and alcohol testing when conducting the tests on which the licensee or other entity relies. By contrast, if a C/V implements an FFD program element that is addressed in this part, but that program element is not relied upon by a licensee or other entity who is subject to this part, then the proposed paragraph would not require the C/V to meet the applicable Part 26 requirements for that FFD program element.

Proposed §26.3(d) would require C/Vs to meet the requirements of proposed Subpart I [Managing Fatigue], if any nuclear power plant licensees rely upon a C/V's fatigue management program element to meet the requirements of Subpart I. The applicability of proposed Subpart I to C/Vs will be discussed with respect to proposed §26.195 [Applicability].

Other provisions of current §26.23 [Contractors and vendors] would either be eliminated from the proposed rule or moved to other sections of the proposed rule. The current requirement for licensees to retain written agreements with C/Vs in the second sentence of §26.23 would be moved to proposed Subpart J [Recordkeeping and Reporting Requirements]. The requirement in current §26.23(a)(1), which requires that individuals who have violated an FFD program must not be assigned to work within the scope of this part without the knowledge and consent of the licensee, would be addressed in proposed Subpart C [Granting and Maintaining Authorization]. The audit requirement contained in current §26.23(b) would be addressed in proposed §26.41(d) [Contracts]. The current requirements would be moved to different sections of the proposed rule to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B, by grouping related requirements together in one section or subpart that addresses similar topics.

Proposed §26.3(e) would retain and update the requirements of current §26.2(c) to be consistent with revisions to related sections of the proposed rule as well as related parts of this chapter. Combined operating license holders (under Part 52 of this chapter) before the Commission has made the finding under §52.103 of this chapter would continue to be subject to the rule, as well as combined license applicants who have received authorization to construct under §50.10(e)(3), construction permit holders (under Part 50 of this chapter), construction permit applicants who have received authorization to construct under §50.10(e)(3), and holders of manufacturing licenses (under Part 52 of this chapter). For consistency, the proposed paragraph would also replace the current cross-references to other sections of the rule with updated cross-references to the related sections in the proposed rule and replace some terms used in the current paragraph with new terms that would be used throughout the proposed rule. For example, the term, “chemical testing,” would be replaced with “drug and alcohol testing,” and “appeals” would be replaced with “review” for reasons that will be discussed below related to proposed §26.31 [Drug and alcohol testing] and proposed §26.39 [Review process for fitness-for-duty violations], respectively. Other new terms in the proposed rule that would replace some of the terms used in the current rule are discussed with respect to proposed §26.5 [Definitions].

Proposed §26.3(f) would retain the second sentence of current §26.2(b) because it addresses entities who would not be subject to the proposed rule. The first sentence of current §26.2(b), which addresses individuals who are not subject to the rule, would be moved to proposed §26.25 [Individuals subject to the fitness-for-duty program] for organizational clarity in the proposed rule.

Section 26.5 Definitions

Proposed §26.5 [Definitions] would amend current §26.3 [Definitions] to (1) clarify some definitions; (2) make the listed terms and their definitions more consistent with those used by other Federal agencies (including the Substance Abuse and Mental Health Services Administration and the Department of Transportation); (3) define new terms used in other sections of the proposed rule; and (4) move definitions into this section from current Section 1.2 of Appendix A to 10 CFR Part 26, which contains definitions of important terms used in Appendix A to Part 26. The proposed rule would also eliminate six terms in current §26.3 and Section 1.2 of Appendix A to Part 26 because they would be fully defined in the text of the proposed rule or would no longer be used in the proposed rule. In addition, the proposed rule would eliminate redundant definitions of some terms, which appear in both current §26.3 and Section 1.2 in Appendix A to Part 26. Finally, some definitions would be revised to make them simpler and easier to understand, consistent with the Agency's commitment to using plain language. For example, some definitions in the current rule include requirements that are also contained in other sections of the rule. In these instances, the proposed rule would eliminate the requirements that are embedded in the definitions, but retain the definitions in this section. The requirements would be moved to the related sections of the rule for organizational clarity.

The majority of the proposed changes to this section would be made as a result of adding new requirements for urine drug testing, including specimen validity testing, to the proposed rule. The proposed rule would incorporate advances in the science and technology of urine drug testing that are based on the most recent revision to the HHS Guidelines, as published in the Federal Register on April 13, 2004 (69 FR 19643). These proposed changes would require adding terms to proposed §26.5, modifying a number of the terms that are used

in the current rule, and revising the definitions of some terms in the current rule that would also be used in the proposed rule, as follows:

The proposed rule would add several new terms to refer to urine specimens that have characteristics that are inconsistent with those expected of normal human urine, as identified through validity testing. The proposed terms would include “adulterated specimen,” “dilute specimen,” “substituted specimen,” and “invalid result.” The proposed rule would also add the term, “oxidizing adulterant,” to refer to one class of substances that may be used to adulterate urine specimens. These new terms and proposed definitions would be adapted from the HHS Guidelines.

The proposed rule also would add several terms that are associated with new requirements for maintaining quality control of urine specimen validity and drug testing, such as the term, “quality control sample.” The proposed rule would also add definitions of the terms, “calibrator,” “control,” and “standard,” to distinguish among the types of quality control samples that are associated with urine specimen testing in Subparts F [Licensee Testing Facilities] and G [Laboratories Certified by the Department of Health and Human Services] of the proposed rule.

The proposed rule would change certain terms that describe drug and alcohol tests to reflect the addition of urine specimen validity testing requirements. The changes would include replacing the term, “initial or screening test,” with more specific terms to distinguish between drug testing and testing for urine specimen validity. The terms, “validity screening test,” “initial drug test,” and “initial validity test,” would be added to refer to the first tests of a urine specimen that would be performed to determine whether a urine specimen is free of drugs and drug metabolites and has the expected characteristics of normal urine, or whether further testing of the specimen is required. The proposed rule would also modify the definition of “initial drug

test" in the current rule to eliminate the requirement that the test must be performed using immunoassay techniques because that requirement would be addressed in the text of the proposed rule. The proposed rule would replace the general term, "confirmatory test," in the current rule with the more specific terms, "confirmatory drug or alcohol test" and "confirmatory validity test." In addition, the definitions of these terms in the proposed rule would not include requirements for the methods to be used in performing confirmatory tests because these requirements would be addressed in the text of the proposed rule. Therefore, the requirement that confirmatory drug testing be performed using gas chromatography/mass spectrometry (GC/MS) testing would be removed from the definition. The proposed rule would also eliminate the reference to GC/MS testing of blood samples for confirmatory alcohol testing in the definition of "confirmatory drug or alcohol test" because the proposed rule would no longer give donors the option to provide a blood sample for alcohol confirmatory testing, as discussed with respect to proposed §26.83(a).

The proposed rule would modify several terms that are used in the current rule to describe the results of drug and alcohol testing, in order to reduce the number of terms, increase consistency with terms used by other Federal agencies, and address the addition of urine specimen validity testing requirements. Among these changes, the proposed rule would add the term "non-negative test result." The term, "non-negative," would be used to refer to any adverse test result from the different types of testing that would be required under the proposed rule. For example, the proposed rule would use "non-negative" to refer to positive results from alcohol testing as well as results of drug and validity tests of urine specimens that indicate the presence of drugs or drug metabolites, and/or that the specimen may be adulterated, dilute, substituted, or invalid. The term, "presumptive positive test result," would be eliminated from the proposed section because it would no longer be used in the rule text. The updated term,

“non-negative initial test result,” would be used in the rule text instead. The proposed rule would also change the term, “confirmed positive test,” to “confirmed test result” to clarify that this term refers to the results of the MRO’s review of drug and validity tests of urine specimens and to positive results of a confirmatory alcohol test, rather than to a type of testing. The proposed rule would also remove the reference to testing of blood specimens for alcohol that is contained in the current definition of “confirmed positive test” from the definition of “confirmed test result” because blood specimens would no longer be collected at the donor's request for confirmatory alcohol testing, as discussed with respect to proposed §26.83(a).

The proposed rule would also add two terms that refer to testing for very low levels of drugs, drug metabolites, or adulterants in a urine specimen, “limit of detection” (LOD) and “limit of quantitation” (LOQ). The proposed definitions of these terms would be adapted from the HHS Guidelines.

In addition, the definitions of two terms in the current rule would be modified to be consistent with the new drug and alcohol testing terminology that would be used throughout the proposed rule. The proposed rule would amend the definition of “cutoff level” to refer to “non-negative,” rather than “positive,” test results to clarify that the term is also applicable to the interpretation of results from specimen validity testing. And, the definition of “Medical Review Officer” (MRO) would be amended to refer to a “non-negative” test result, rather than a “positive” test result, to clarify that the MRO would review validity test results in addition to drug test results.

The proposed rule would also add several terms that would be necessary to implement the proposed requirements contained in two new subparts of the regulation, proposed Subpart C [Granting and Maintaining Authorization] and proposed Subpart I [Managing Fatigue]. The proposed rule would add six new terms that are related to the requirements of

proposed Subpart C. The term, “potentially disqualifying fitness-for-duty (FFD) information,” would be added to refer to the types of information that licensees and other entities who are subject to the rule would consider when deciding whether to grant or maintain an individual’s authorization to have the types of access or perform the job duties that are listed in proposed §26.26(a). The proposed rule would also add definitions for four terms that are used within the definition of “potentially disqualifying FFD information,” including “substance abuse;” “legal action;” “employment action;” and “reviewing official.” The term, “best effort,” would also be added to refer to the actions that a licensee or other entity who is subject to the rule must take to obtain the information that is necessary to complete a suitable inquiry and employment history check, as discussed with respect to proposed §26.63(a).

The proposed rule would also add several terms that are necessary to implement the requirements of proposed Subpart I [Managing Fatigue]. These terms would include “fatigue,” “acute fatigue,” and “cumulative fatigue,” which refer to the degradation in an individual’s cognitive (mental) and motor (physical) functioning resulting from inadequate rest within the past 24 hours or over successive days and weeks, respectively. The proposed rule would use the term, “alertness,” to refer to an individual’s ability to remain awake and sustain attention, which is adversely affected by fatigue. The term, “circadian variation in alertness and performance,“ would be added to define a factor that licensees would consider when conducting a fatigue assessment under proposed §26.201 [Fatigue assessments]. The proposed rule would also add the term, “increase in threat condition,” to refer to circumstances in which the proposed rule would provide licensees with some flexibility in implementing the work hour controls of proposed §26.199 [Work hour controls].

The proposed rule would also add eight new terms related to other proposed revisions to the current rule. Specifically, “analytical run” would be added for use in establishing

amended performance testing requirements for licensee testing facilities in proposed §26.137 [Quality assurance and quality control]. The term, “directing,” would be added to clarify new requirements for MRO staff under proposed §26.183(d) and the scope of individuals who would be subject to work hour controls in proposed §26.199(a). For consistency with the use of the term in the related regulations of other Federal agencies, the term, “donor,” would replace the current terms that are used to refer to an individual from whom a specimen is collected for drug or alcohol testing. The term, “nominal,” would be added to refer to the leeway in the time periods within which certain requirements must be met, such as the requirement for annual FFD refresher training in proposed §26.29(c)(2). The term, “other entity,” would be added to refer to organizations who would be subject to Part 26, but who are not licensed by the NRC, including, but not limited to, the organizations who hold the NRC certificates or permits listed in proposed §26.3 [Scope]. The terms, “formula quantity” and “strategic special nuclear material” (SSNM), would be defined consistently with the definitions of the same terms in 10 CFR 70.4. The term, “subversion and subvert the testing process,” would be added to clarify the language of new provisions related to urine specimen validity testing, as discussed with respect to proposed §26.31(d)(3)(i), and new sanctions that would be imposed on individuals who are subject to the proposed rule, in proposed §26.75(b).

Proposed §26.5 would also retain and amend a number of other definitions currently contained in §26.3 and Section 1.2 in Appendix A to Part 26, as follows.

The proposed rule would revise the current definition of “aliquot” to clarify that an aliquot is a representative sample of a urine specimen that may be used for testing. The amended definition would be consistent with the same definition in the HHS Guidelines.

The proposed rule would simplify the current definition of “blood alcohol concentration” (BAC) by deleting references to the instruments and devices that licensees and other entities

are permitted to use for alcohol testing. The text of proposed §26.91 [Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use] would specify acceptable devices for alcohol testing under the proposed rule.

The proposed rule would revise the definition of “category IA material” to conform with the current definition contained in 10 CFR 74.4.

The proposed rule would expand the definition of “chain of custody” to indicate that the terms “chain of custody” and “custody and control” are synonymous. This proposed change would be made in response to stakeholder requests during the public meetings discussed in Section V.

The definition of “collection site” would be modified to include a reference to oral fluids as specimens that are acceptable for initial alcohol testing. The basis for permitting the use of oral fluids for initial alcohol testing is discussed with respect to proposed §26.83(a).

The proposed rule would replace the term, “collection site person,” with the term, “collector,” to simplify the terminology used to refer to individuals who collect specimens for testing and for consistency with the terminology used by other Federal agencies. In addition, the definition would no longer include the qualifications required for collectors because they would be specified in proposed §26.85 [Collector qualifications and responsibilities].

The proposed rule would add the term “contractor/vendor” (C/V) and combine the definitions of “contractor” and “vendor” in the current rule, because the proposed rule would not distinguish between the two types of entities.

The proposed rule would update the definition of “HHS-certified laboratory” to reference the most recent version of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs.

In addition, the proposed rule would simplify the definition of “licensee testing facility” by eliminating the reference to collecting specimens for alcohol testing in the current definition, because alcohol testing typically occurs at a collection site, rather than at the licensee testing facility.

Finally, the proposed rule would eliminate six terms that are defined in current §26.3 and Section 1.2 in Appendix A to Part 26. Specifically, the proposed rule would eliminate “followup testing,” “random test,” “suitable inquiry,” “reason to believe,” and “split specimen” because the text of the proposed rule defines them in the section where each term is used. The proposed rule would also eliminate the term, “permanent record book,” in current Section 1.2 in Appendix A to Part 26 because laboratories now use other mechanisms to maintain testing records. Therefore, this term would no longer be used in the proposed rule.

Section 26.7 Interpretations

Proposed §26.7 [Interpretations] would retain current §26. 4 [Interpretations] but move the qualifying phrase, “other than a written interpretation by the General Counsel,” to the end of the sentence to improve the clarity of the sentence. This proposed change would be made in keeping with the Commission’s commitment to using plain language in its regulations and to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B.

Section 26.8 Information collection requirements: OMB approval

Proposed §26.8 [Information collection requirements: OMB approval] would amend current §26.8 [Information collection requirements: OMB approval] to reflect the modified sections of the proposed rule in which recordkeeping requirements would be incorporated.

Section 26.9 Specific Exemptions

Proposed §26.9 [Specific Exemptions] would revise current §26.6 [Exemptions] to include the citation of 10 CFR 50.12 and 70.17. This proposed change would be made to ensure consistency between Part 26 and these related requirements.

Section 26.11 Communications

Proposed §26.11 [Communications] would be added to improve consistency with similar sections in other parts of 10 CFR and ensure that communications with the NRC are addressed and, therefore, processed properly.

Subpart B – Program Elements

Section 26.21 Fitness-for-duty program

Proposed §26.21 [Fitness-for-duty program] would require that licensees and other entities who are subject to the rule must establish, implement, and maintain FFD programs that comply with the applicable requirements of this part. This statement would be added to serve as an introduction to the remaining text of the proposed rule, consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, as

discussed in Section IV. B. The term, “applicable,” would be included in this sentence because not all the requirements in the proposed regulation would apply to all the entities listed in proposed §26.3(a)–(d). For example, the requirements in proposed Subpart I [Managing Fatigue] would apply only to nuclear power plant licensees and any C/Vs upon whom they rely to meet the requirements of this part, as discussed with respect to proposed §26.195 [Applicability]. As another example, the proposed rule would retain the current requirement in §26.2(c), which states that nuclear power plant construction permit holders must establish a drug and alcohol testing program that includes random testing, but would not require these entities to meet the requirements of the proposed regulation related to drug and alcohol testing, including, but not limited to, proposed §26.31 [Drug and alcohol testing] and proposed Subpart E [Collecting Specimens for Testing].

The second sentence of the proposed paragraph, which is based on current §26.23(b), would retain permission for licensees and other entities to rely upon a C/V’s FFD program or program elements to meet the requirements of this part, if the C/V’s FFD program or program element meets the applicable requirements of this part. The other requirements contained in current §26.23 [Contractors and vendors] are discussed with respect to proposed §26.23 [Performance objectives].

Section 26.23 Performance objectives

Proposed §26.23 [Performance objectives] would amend current §26.10 [General performance objectives], as follows:

The proposed rule would amend current §26.10(a). The proposed rule would divide the performance objectives contained in current §26.10(a) into two paragraphs (proposed §26.23(a)

and (b), respectively) to clarify that the performance objective of assuring that personnel are trustworthy and reliable is separate and distinct from the performance objective of assuring that personnel are fit for duty.

Proposed §26.23(a) would amend current §26.10(a) to emphasize the NRC's intent that FFD programs provide "high," rather than "reasonable," assurance that persons who are subject to this part are trustworthy and reliable as demonstrated by the avoidance of substance abuse and the adverse behaviors that accompany it. To reduce the risk of an insider threat, maintain public health and safety, and provide for the common defense and security in the post-September 11, 2001, threat environment, the NRC has placed an increased emphasis on the trustworthiness and reliability of individuals who have access to certain types of sensitive information, certain types of radiological materials, and protected areas in nuclear power plants. These are the same individuals who would be subject to the proposed rule. Because these individuals have unimpeded access to sensitive information and safety equipment and systems, their trustworthiness and reliability are essential. Substance abuse by such individuals presents an unacceptable risk to public health and safety and the common defense and security in several ways.

First, substance abuse increases the likelihood that such individuals may pose an insider threat by increasing an individual's vulnerability to coercion. Under 10 CFR 73.1, a passive insider is defined as an individual who obtains or attempts to obtain safeguards or other relevant information, such as a nuclear power plant's physical configuration and design, and who does not have a functional or operational need to know such information. Section 73.1 defines an active insider as a knowledgeable individual who, while within the protected area of a nuclear power plant in an unescorted status, takes direct action to facilitate entrance and exit, disable alarms and communications, and/or participates in a violent attack. An individual who

uses illegal drugs may be coerced into cooperating, actively or passively, with a terrorist in an attempt to commit radiological sabotage if, for example, the terrorist were to threaten the individual with revealing his or her illegal drug use or was somehow able to withhold drugs from an individual who is addicted.

Second, an individual's judgement and self-control are impaired while an individual is abusing drugs or alcohol. When an individual is intoxicated from abusing any of the substances for which testing is conducted under Part 26, including alcohol, the individual is more likely to inadvertently reveal sensitive information that terrorists could use in a radiological sabotage attempt than when he or she is not intoxicated.

Third, the use of illegal drugs establishes that an individual is willing to disobey the law, thus indicating that the individual will disregard other rules and regulations. The use of illegal drugs raises questions about the individual's trustworthiness and reliability in terms of scrupulously following the regulations, procedures, and other requirements, such as safeguards requirements, that ensure the protection of public health and safety.

Many provisions of the current rule provide means to identify and reduce the risks posed by any individuals whose substance abuse casts doubt on their trustworthiness and reliability. In combination with other measures the NRC has taken since September 11, 2001, a number of the proposed changes to the current rule would provide further assurance that individuals who are subject to the rule are trustworthy and reliable. Proposed changes to strengthen the effectiveness of the rule in assuring individuals' trustworthiness and reliability include, but are not limited to:

(1) Adding requirements for specimen validity testing to identify individuals who are willing to attempt to subvert the testing process, and so may be willing to subvert other rules

and regulations that are important for public health and safety and the common defense and security;

(2) Increasing the rigor of the evaluations that licensees and other entities must perform before granting authorization to an individual who has previously violated Part 26 requirements to ensure that the individual has ceased abusing drugs or alcohol; and

(3) Imposing more stringent sanctions on individuals who violate Part 26 requirements, including, but not limited to, permanently denying authorization to have the types of access and perform the job duties listed in proposed §26.25(a) to any individual who attempts to subvert the drug and alcohol testing process.

The NRC believes that implementation of these provisions of the proposed rule, in addition to the other, related measures the Agency has taken in the post-September 11, 2001, threat environment, would provide high assurance that individuals who are subject to the rule are trustworthy and reliable.

Proposed §26.23(b) would retain the performance objective of providing “reasonable” assurance that personnel are fit for duty, which appears in current §26.10(a). By contrast to the performance objective of providing high assurance that individuals are trustworthy and reliable, the use of the term, “reasonable,” to describe the level of assurance required by the rule reflects the NRC’s awareness that an individual’s fitness at any particular moment in time may be affected by many different factors. Some of these factors may be difficult for the licensee or other entity to detect and many (such as a transitory illness) may not warrant management action or the imposition of sanctions because they would not pose a significant risk to public health and safety.

One difference between providing “high” assurance of trustworthiness and reliability and “reasonable” assurance that individuals are not impaired lies in the sanctions that the proposed rule would require licensees and other entities to impose on individuals who demonstrate questionable trustworthiness and reliability compared to the management actions licensees would be expected to take with individuals who may be impaired. For example, if an individual demonstrates dishonesty by attempting to bring a substitute urine specimen to the collection site with a clear intent to subvert the testing process or demonstrates a willingness to break the law by possessing illegal drugs on site, the proposed rule (under proposed §§26.75(b) and 26.75(c), respectively) would require the licensee or other entity to terminate the individual’s authorization to have the types of access and perform the job duties that are listed in proposed §26.25 [Individuals subject to the fitness-for-duty program]. Terminating the individual’s authorization would be necessary to provide high assurance that the individual could pose no further risk to public health and safety or the common defense and security. By contrast, the current and proposed rules would not require a licensee or other entity to terminate an individual’s authorization if he or she is mentally or physically impaired while on duty from such transitory causes as illness and emotional stress resulting from a family problem. For example, an individual who arrives at work with a severe migraine headache may suffer impairment on the job that would adversely affect the individual’s ability to perform his or her duties safely and competently while the headache persists. The proposed (and current) rule (under proposed §26.77(b)(3) and current §26.27(b)(1), respectively) would require the licensee or other entity to take action to prevent the individual from performing the job duties that require the individual to be subject to this part, if the individual’s fitness is questionable. These actions could include, for example, assigning the individual to other duties until medication brings the headache under control or sending the individual home until the headache resolves. Such actions would meet

the performance objective of providing reasonable assurance that the individual is fit when he or she resumes his or her normal duties. However, it would be unreasonable for a licensee's FFD policy to impose sanctions on the individual, such as terminating his or her authorization. Sanctions could have no deterrent effect on the recurrence of the individual's headache, which is one purpose of including requirements for minimum sanctions in Part 26. In addition, there would not be any continuing risk to public health and safety from permitting the individual to resume his or her duties once the headache is resolved.

Another difference between the performance objectives of providing "high" assurance of trustworthiness and reliability and "reasonable" assurance that the individuals who are subject to the proposed rule are fit for duty lies in the severity of the enforcement actions that the NRC would be likely to take against an FFD program that failed to meet these performance objectives. The NRC's enforcement actions would be severe in the case of an FFD program that, for example, granted authorization to an individual who had previously had his or her authorization permanently denied under proposed §26.75(b) but would be unlikely to take enforcement action in the case of an FFD program that failed to remove an individual who was experiencing impairment related to family stress from his or her duties under proposed §26.77(b)(3).

Proposed §26.23(c) would retain the performance objective in current §26.10(b), which is to "provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of this part," but would replace the phrase, "perform activities within the scope of this part," with the phrase, "perform the job duties that require them to be subject to this part." The proposed rule would make this change for clarity in the language of the rule. As discussed further with respect to proposed §26.25 [Individuals subject to the fitness-for-duty program], the proposed rule would require that certain individuals must be subject to an FFD

program based on their job duties, which include not only performing activities, such as measuring, guarding, or transporting Category IA material, but also having access to certain locations, material, and sensitive information, such as nuclear power plant protected areas, Category IA material, procedures and records for safeguarding SSNM, and the drug test results of an individual who was tested before the MRO reviews the drug test results. Therefore, the phrase, "perform the job duties that require them to be subject to this part," would be more accurate. Replacing the current phrase with the more accurate phrase would be consistent with Goal 6 of the rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B.

Proposed §26.23(d) would amend current §26.10(c) to require that FFD programs must provide reasonable assurance that the workplaces that are subject to this part are free from the presence and effects of illegal drugs and alcohol. The proposed rule would revise the current performance objective to "have a goal of achieving a drug-free workplace and a workplace free of the effects of such substances" for several reasons. First, the terms, "drug-free" and "free from the effects of such substances," do not accurately capture the NRC's intent with respect to this performance objective. These terms could be misunderstood as requiring FFD programs to have the goal of preventing any drugs and their effects from being present in the workplace, which could include medications that individuals who are subject to the rule may take to treat health problems. Therefore, the proposed rule would replace "drug-free" and "free of the effects of such substances" with the more specific phrase, "free from the presence and effects of illegal drugs and alcohol" to refer to the specific substances that would be proscribed. The proposed revision would clarify that the NRC does not intend for FFD programs to prohibit individuals from taking the medications they need to maintain their health or bringing those

medications to the workplace. This proposed change would be made to meet Goal 6 of the rulemaking, which is to improve clarity in the organization and language of the rule.

The proposed performance objective would also replace the phrase, “have a goal of,” in the current rule with the phrase, “provide reasonable assurance,” which more accurately captures the intent of this performance objective. The phrase, “have a goal of,” would be eliminated because proposed §26.23(d) is a performance objective and, therefore, the phrase is unnecessary. This proposed change would be made to meet Goal 6 of the rulemaking, which is to improve clarity in the organization and language of the rule, without changing the intended meaning of the performance objective.

Proposed §26.23(e) would be added to require licensees and other entities to provide reasonable assurance that the effects of fatigue and degraded alertness on individuals’ abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety. This proposed performance objective would be added to specify the objective of the requirements concerning worker fatigue that would be added to the proposed rule. Worker fatigue cannot be measured or controlled with precision, and licensees and other entities do not have direct control over all matters that may influence worker fatigue. Therefore, proposed §26.23(e) would establish a “reasonable assurance” criterion for the proposed performance objective. Worker fatigue can result from many causes (e.g., work hours, sleep disorders, demands outside the workplace). In addition, individuals differ in their responses to conditions that cause fatigue. As a consequence, work hour limits alone do not address all causes of fatigue, nor do they prevent fatigue from work hours for all workers. Contemporary methods for addressing worker fatigue (e.g. Rogers, 1996, 1997; Hartley, 1998; Carroll, 1999) are commonly referred to as “fatigue management” programs and use diverse methods (e.g., training, behavioral observation, fatigue countermeasures) in addition to work hour controls to

prevent, detect, and mitigate fatigue. Accordingly, proposed §26.23(e) would establish a performance objective of reasonable assurance that effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are "managed" commensurate with maintaining public health and safety. The proposed performance objective would permit licensees and other entities to apply risk-informed fatigue management controls for individuals consistent with the significance of their work activities to the protection of public health and safety.

Section 26.25 Individuals subject to the fitness-for-duty program

Proposed §26.25 [Individuals subject to the fitness-for-duty program] would be added to group together in one section the provisions of the proposed rule that specify the individuals who must be subject to the FFD program, based on their job duties, and those who would not be subject to the FFD program. This proposed change would be made to meet Goal 6 of the rulemaking, which is to improve clarity in the organization and language of the rule, by grouping related requirements together within the rule.

Proposed §26.25(a)(1)–(a)(3) would amend the portions of current §26.2(a) and (d) that describe the individuals whose job duties require them to be subject to Part 26 by presenting the requirements in separate paragraphs. This organizational change would be made to make it easier for users to locate these requirements within the rule text and to support cross-referencing to these paragraphs from other portions of the rule, so that it is unnecessary to repeat the relevant list of job duties each time the rule refers to a specific group of individuals, as the organization of the current rule has required [see, for example, current §26.27(a)(1), (b)(2), and (b)(3)]. This proposed change would be made to meet Goal 6 of the rulemaking,

which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B.

The proposed rule would add §26.25(a)(4) to clarify the NRC's original intent that FFD program personnel must be subject to the FFD program. Although current Section 2.3 in Appendix A to Part 26 requires licensees to carefully select and monitor individuals who are responsible for administering the drug and alcohol testing program based upon the highest standards of honesty and integrity, some licensees' testing programs did not include all of the FFD program personnel who the NRC originally intended to be subject to testing. The proposed change would be made to clarify the NRC's original intent because the actions of these individuals have an ongoing effect on public health and safety and the common defense and security as a result of their responsibility to ensure that FFD programs are effective. In addition, these individuals' actions affect the confidence that the public, management, and individuals who are subject to testing have in the integrity of the program and the accuracy and reliability of test results. Individuals who are involved in the day-to-day operations of an FFD program are in a position to permit substance abusers to remain undetected. For example, specimen collectors could inadvertently commit errors when testing others as a result of being impaired from drug or alcohol abuse or intentionally omit testing an individual because of motives associated with maintaining a collector's substance abuse or empathy with an abuser. Furthermore, 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 specimen collectors to the testing pool after investigating an allegation and determining that two collectors were substance abusers. In another instance, a contracted MRO who was not in the testing pool was reported to be an alcoholic and an abuser of prescription drugs. Some MROs who provide their services to other Federally regulated

industries have also been identified as substance abusers. Therefore, the proposed revision to current §26.2(a) would fulfill the NRC's original objective and require licensees and other entities to extend their programs to include FFD personnel who (1) can link test results with the individual who was tested before an FFD policy violation determination is made, including, but not limited to the MRO; (2) make determinations of fitness; (3) make authorization decisions; (4) are involved in selecting or notifying individuals for testing; or (5) are involved in the collection or on-site testing of specimens. Although job titles and responsibilities may differ among different Part 26 FFD programs, examples of FFD program personnel who would be subject to Part 26 under the proposed rule would include, but would not be limited to, the following: the FFD program manager under proposed §26.25(a)(4)(i)–(a)(4)(v); the MRO and MRO staff under proposed §26.25(a)(4)(i); the licensee's or other entity's reviewing officials under proposed §26.25(a)(4)(iii); specimen collectors under proposed §26.25(a)(4)(v); SAEs who are under contract to or employed by the FFD program under proposed §26.25(a)(4)(ii); and licensee testing facility personnel under proposed §26.25(a)(4)(v). In some cases, information technology personnel who design and implement software programs for selecting individuals for random testing may also be subject to the rule under proposed §26.25(a)(4)(iv) if such personnel have knowledge of who will be selected for random testing or the ability to affect the selection of specific individuals for random testing.

Proposed §26.25(b)(1)–(b)(3) would be added to group together in one paragraph the proposed rule's provisions that identify individuals who would not be subject to the rule. This proposed change would be made to meet Goal 6 of the rulemaking, which is to improve clarity in the organization and language of the rule.

A new provision, proposed §26.25(b)(1), would be added to the rule as a result of extensive discussions with industry stakeholders at the public meetings mentioned in Section V.

Industry stakeholders expressed strong concern that the related language in the Affirmed Rule (which was also discussed in Section V), which delineated the FFD program personnel who must be subject to the Part 26, was too broad. Stakeholders agreed that FFD program personnel who work on site and are involved in the day-to-day operations of the FFD program should be subject to the rule. However, the stakeholders noted that the language used in the Affirmed Rule was so vague that it could be interpreted as requiring, for example, that off-site human resources staff at a licensee's or other entity's corporate offices, who may have access to some FFD information about individuals, must be covered, as well as any medical or treatment personnel, and their managers, at a hospital or substance abuse treatment facility who provide an occasional FFD program service. These interpretations of the intent of the Affirmed Rule provisions would be incorrect.

The stakeholders also strongly disagreed with the requirement in the Affirmed Rule that some FFD program personnel who maintain offices at other locations than a licensee's or other entity's facilities and are not involved in day-to-day program operations, such as EAP counselors and some contract MROs, should be subject to the rule. The stakeholders indicated that they believe the honesty and integrity of such off-site personnel is maintained through their professions' oversight and standards, with the result that requiring these individuals to be subject to the rule would create a significant and unnecessary regulatory burden. Stakeholders stated that the regulatory burden would result from (1) the significant logistical difficulties involved in ensuring that these individuals are subject to behavioral observation and drug and alcohol testing, and (2) excessive costs to hire additional MRO(s) to review any non-negative drug test results from MRO(s) who serve the FFD program.

Based on the stakeholders' input, "lessons learned" from FFD program experience since the rule was first implemented, the experience gained by other Federal agencies and their

regulated industries, and the continuing need to ensure that FFD program personnel meet the highest standards of honesty and integrity, the NRC added §26.25(b)(1) to the proposed rule. The proposed paragraph would exclude from the rule individuals who may be called upon to provide an FFD program service to a licensee or other entity in special circumstances and who meet all of the following criteria:

(1) They are not employed by the licensee or other entity;

(2) They do not routinely provide services to the licensee's or other entity's FFD program; and

(3) They do not normally work at a licensee's or other entity's facility.

Examples of individuals who would not be subject to the rule under the proposed provision may include, but would not be limited to, a nurse at a local hospital who collects a single specimen for a post-event test from an individual who has been injured and a counselor at a residential substance abuse treatment facility who performs behavioral observation of a patient while the individual is in residence. Personnel who meet the three criteria specified in the proposed paragraph would be excluded from the FFD program because the limited nature of their involvement with the FFD program makes it unlikely that they would be subject to coercion or influence attempts to subvert the testing process and the NRC is not aware of any reports indicating that these types of individuals have been involved in any adverse incidents. Therefore, the NRC concurs with the stakeholders that requiring such individuals to be subject to the FFD program would be unnecessary.

However, proposed §26.25(a)(4) would require MROs and SAEs to be subject to Part 26 (see the discussion of proposed §26.187 [Substance abuse expert] in Section VI of this document for a detailed description of the SAE's roles and responsibilities under the FFD

program), as well as any EAP counselor who serves as the SAE for a licensee's or other entity's FFD program. Individuals who serve in these positions play the key roles of determining whether a non-negative drug test result is an FFD policy violation (i.e., the MRO under proposed §26.185) and whether an individual is fit to safely and competently perform the job duties that require the individual to be subject to this part (i.e., the SAE). Although the NRC recognizes the significant logistical difficulties and costs that may be associated with covering these individuals, the NRC concluded that MROs and SAEs play such critical roles in the effective functioning of an FFD program that ensuring their continuing honesty and integrity by requiring them to be subject to the rule is warranted and invites further comment on these provisions.

Proposed §26.25(b)(2) and (3) would retain the first sentence of current §26.2(b) but divide it into two paragraphs. This organizational change would be made to make it easier to locate these requirements within the rule text and to support cross-referencing to these paragraphs from other portions of the rule. The second sentence of current §26.2(b) would be moved to proposed §26.3(e) rather than retained in this paragraph because it addresses entities who would not be subject to the rule, rather than individuals. The proposed changes would be made to meet Goal 6 of the rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B.

Proposed §26.25(c) would be added to provide that persons who are covered by a program regulated by another Federal or State agency that meets the performance objectives of Part 26 need not also be covered by a licensee's or other entity'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 facilities have implemented the Department of Transportation's (DOT) drug and alcohol testing requirements [49 CFR Part 40 -

65 FR 41944, August 9; 2001]. This proposed revision would reduce the burden on some individuals who are currently subject to Federal and State programs with requirements that duplicate those of Part 26. Minor differences in specific program requirements for conducting drug and alcohol testing would be unlikely to adversely affect the ability of a licensee's or other entity's FFD program to meet the performance objectives of this part. The licensee or other entity would continue to be responsible for implementing any Part 26 program elements that may not be addressed by the alternate Federal or State program. These program elements may include, but would not be limited to, providing behavioral observation and initiating for-cause testing, if necessary, when an individual who is covered by an alternate program is on site at a licensee's or other entity's facility and is performing the job duties that require the individual to be subject to the rule, as well as immediate removal from duty of persons whose fitness may be questionable.

Proposed §26.25(c)(1)–(c)(6) would list the necessary characteristics of an alternative Federal or State program that, under the proposed rule, licensees and other entities could rely upon to satisfy the requirements of this part for an individual who is subject both to Part 26 and an alternative program. Proposed §26.25(c)(1) and (3) would permit licensees and other entities to rely on the alternative program to meet the proposed rule's drug testing requirements if the alternative program tests for the drugs and drug metabolites that are specified in the proposed rule at or below the cutoff levels established in the proposed rule and an HHS-certified laboratory conducts the program's specimen validity and drug testing. Similarly, proposed §26.25(c)(2) would permit licensees and other entities to rely on the alternative program to meet the proposed rule's alcohol testing requirements if the alternative program's alcohol testing procedures and devices meet the proposed rule's requirements and the alternative program uses cutoff levels that are at least as stringent as those specified in

proposed §26.103(a). Proposed §26.25(c)(4) would permit the licensee or other entity to rely on an alternative program's FFD training if that training addresses the knowledge and abilities listed in proposed §26.29(a)(1)–(a)(10). Proposed §26.25(c)(5) would permit licensees and other entities to rely on the alternative program to meet the proposed rule's requirements for an impartial and objective procedure for the review and reversal of any findings of an FFD violation if the alternative program provides such a procedure. And, finally, if the licensee or other entity relies on the alternative program, proposed §26.25(c)(6) would require the licensee or other entity to ensure that the alternative program would inform the licensee or other entity of any FFD violations.

These proposed provisions would be consistent with the current and proposed rules' approaches to permitting licensees and other entities to rely on C/V FFD programs and program elements to meet the requirements of this part if the C/V's program or program element meets the requirements of this part, as discussed with respect to proposed §26.21 [Fitness-for-duty programs]. In general, permitting licensees and other entities to rely on FFD programs and program elements that are implemented by others, when those programs or program elements meet the requirements of this part, would fulfill the rule's performance objectives and improve Part 26 by eliminating or modifying unnecessary requirements, which is Goal 5 of this rulemaking, as discussed in Section IV. B. However, an important difference between the proposed rule's permission for licensees and other entities to rely on the programs of other Federal and State agencies, compared to the proposed rule's permission for licensees and other entities to rely on C/V programs, is that the proposed rule would not require licensees and other entities to audit the alternate Federal and State programs under proposed §26.41 [Audits and corrective action]. Auditing Federal and State programs would be unnecessary because these programs are subject to other, equally effective audit and inspection

requirements. Relieving licensees and other entities who are subject to this part from an audit requirement also would be in keeping with Goal 5 of this rulemaking.

Proposed §26.25(d) would be added to clarify that individuals who have applied for authorization to perform job duties that would require them to be subject to Part 26 would also be subject to some provisions of the proposed rule. The current Part 26 requires an applicant for authorization to provide a written statement related to his or her past activities under this part in current §26.27(a)(1); provide permission to the licensee to conduct a suitable inquiry in current §26.27(a)(2); and submit to pre-access testing in current §26.24(a)(1). The proposed rule would impose similar requirements on applicants and add others, such as random testing during the short time period that falls between when a licensee or other entity collects specimens for a pre-access test and then grants authorization to the individual. Therefore, proposed §26.25(d) would ensure the internal consistency of the proposed rule and would meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Section 26.27 Written Policy and Procedures

Proposed §26.27 [Written policy and procedures] would reorganize and amend current §26.20 [Written policy and procedures]. The proposed rule would reorganize the current section to divide into separate paragraphs the requirements related to the FFD policy and those related to FFD program procedures that are intermixed within the current section. The proposed organizational change would be made so that the requirements related to the FFD policy and procedures would be easier to locate within this section, consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B.

Proposed §26.27(a) [General] would amend the first paragraph of current §26.20, which requires licensees to establish and implement written policies and procedures designed to meet the performance objectives and specific requirements of this part and to retain superseded copies of the policies and procedures. The proposed rule would replace the term, “licensee,” in the current rule with the phrase, “licensees and other entities,” because entities other than licensees would be subject to this requirement, as discussed with respect to proposed §26.3 [Scope]. The term, “maintain,” would be added to the current requirement to “establish and implement” written policies and procedures to reflect the fact that licensees and other entities who are subject to Part 26 must occasionally revise FFD program policies and procedures to keep them current when FFD program personnel or other aspects of the FFD program change. The proposed rule would replace “specific” with the term, “applicable,” in the proposed sentence because all the requirements in Part 26 would not apply to all the licensees and other entities who would be subject to the rule, as discussed with respect to proposed §26.3 [Scope]. The proposed rule would also eliminate “designed to” from this sentence because it is unnecessary. The records retention requirements contained in the second sentence of the current paragraph would be moved to proposed §26.213(d) in Subpart J [Recordkeeping and Reporting Requirements], which groups together the recordkeeping and reporting requirements that are interspersed throughout the current rule. These proposed changes to the organization and language of current §26.27 would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B.

Proposed §26.27(b) [Policy] would amend current §26.20(a), which establishes requirements for the written FFD policy. The proposed rule would expand the list of topics that the FFD policy must address. The list of topics to be addressed by the FFD policy would be expanded as a result of discussions with stakeholders during the public meetings described in

Section V. Stakeholders noted that the list of topics in the current rule is incomplete because it does not include many topics about which individuals who are subject to the policy should be aware in order to be able to comply with the policy. Therefore, the proposed rule would add topics to the policy content requirements in current §26.20(a) to ensure that FFD policies will be complete. This proposed change would be made to meet Goal 7 of this rulemaking, as it relates to protecting the due process rights of individuals who are subject to Part 26, as discussed in Section IV. B.

Proposed §26.27(b) would also add requirements for the written FFD policy to be clear, concise, and readily available to all individuals who are subject to the policy because neither the current nor proposed rules require licensees and other entities to provide site-specific FFD training to individuals. However, FFD policies may vary between licensees and other entities with respect to, for example, the sanctions that are applied for confirmed non-negative test results, the cutoff levels used in drug or alcohol testing, or the time periods within which an individual who has been selected for random testing must report to the collection site. Under the proposed rule, the written FFD policy would continue to be the primary means by which a licensee or other entity would communicate local variations in FFD policy. In the past, however, a few individuals challenged determinations that they had violated a licensee's FFD policy on the basis that they were not aware of the specific provisions of the policy to which they were subject. Therefore, the proposed rule would add requirements that the FFD policy must be clear, concise, and readily available in order to promote individuals' awareness of the site-specific FFD policy to which they are subject. This proposed change would be made to meet Goal 7 of this rulemaking, as it relates to protecting the due process rights of individuals who are subject to Part 26.

The proposed rule would also add examples of acceptable methods to make the written policy "readily available" to individuals who are subject to the FFD policy, including, but not limited to, posting the policy in various work areas throughout the licensee's or other entity's facilities, providing individuals with brochures, or allowing individuals to print the policy from a computer. These examples would be added at the request of stakeholders during the public meetings discussed in Section V, and would meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.27(b)(1) would amend the second sentence of current §26.20(a), which requires that "the policy must address the use of illegal drugs and abuse of legal drugs (e.g., alcohol, prescription and over-the-counter drugs)." Proposed §26.27(b)(1) would expand this sentence to require the FFD policy to describe the consequences of on-site or off-site use, sale, or possession of illegal drugs in proposed §26.27(b)(i); the abuse of legal drugs and alcohol in proposed §26.27(b)(ii); and the misuse of prescription and over-the-counter drugs in proposed §26.27(b)(iii). The proposed rule would replace the phrase, "must address," in the current sentence with the phrase, "must describe the consequences of," because stakeholders noted that "must address" is vague during the public meetings discussed in Section V. The phrase, "must describe the consequences of," would clarify the information that the policy must convey to ensure that individuals who are subject to the policy are aware of the consequences of these actions, as specified in the licensee's or other entity's FFD policy. These proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B.

The proposed rule would add a new §26.27(b)(2), which would require the FFD policy to state the time period within which individuals must report to the collection site after being notified that they have been selected for random testing, as specified by the licensee or other

entity. The proposed regulation would not establish a time limit because there are a variety of circumstances among the different entities who are subject to this rule that make it impractical to establish a universal time limit. However, adding the requirement for the licensee's or other entity's FFD policy to establish and convey a time limit would be necessary because some programs have not done so. As a result, circumstances have arisen in which individuals who were selected for random testing intentionally delayed reporting to the collection site in order to take steps to subvert the testing process, such as obtaining an adulterant to bring to the collection site or drinking large amounts of liquid to be able to provide a dilute specimen. Further, the longer that an individual who has abused illegal drugs or alcohol is able to delay providing specimens for testing, the more likely it is that the concentrations of an illegal drug or alcohol in the individual's urine, breath, or oral fluids will decrease due to metabolism, with the result that the concentrations may fall below the cutoff levels for those substances by the time the specimens are collected and the individual's substance abuse would not be detected. Therefore, the proposed rule would require licensees and other entities to establish a time limit within which individuals must report for random testing after they have been notified to improve the effectiveness of FFD programs, consistent with Goal 3 of this rulemaking. The proposed rule would also require the FFD policy to convey this time limit to ensure that individuals are aware of it, given that a failure to appear for testing within the prescribed time limit may lead to the imposition of sanctions under the FFD policy. This proposed change would be made to meet Goal 7 of this rulemaking, as it relates to protecting the due process rights of individuals who are subject to Part 26.

Proposed §26.27(b)(3) would be added to require the FFD policy to inform individuals of the consequences of refusing to be tested and attempting to subvert the testing process. This provision would be added to ensure that persons who are subject to the rule are aware of

proposed §26.75(b), which would require licensees and other entities to impose the sanction of permanent denial of authorization for these actions. Proposed §26.27(b)(3) would be added to protect the due process rights of individuals who are subject to drug and alcohol testing under this part by ensuring that they are informed, in advance, of the licensee's or other entity's policies to which they are subject. Therefore, adding this requirement would meet Goal 7 of this rulemaking with respect to protecting the due process rights of individuals who are subject to Part 26, as discussed in Section IV. B.

Proposed §26.27(b)(4)(i) would amend current §26.20(a)(1), which requires the FFD policy to prohibit the consumption of alcohol within an abstinence period of at least 5 hours preceding "any scheduled working tour." The proposed rule would replace the phrase, "any scheduled working tour," with the phrase, "the individual's arrival at the licensee's or other entity's facility," as a result of stakeholder comments on the language in the current rule at the public meetings discussed in Section V. The stakeholders commented that the current phrase lacks clarity and could be misinterpreted as meaning, "any working tour scheduled by the licensee or other entity." If the phrase was so interpreted, individuals who are subject to the rule may believe that, if they work on a weekend or work overtime that is not part of their normally scheduled working tour, the rule would permit them to consume alcohol within the 5-hour period before they arrive at work, which would be incorrect. Therefore, the language of the proposed rule would be revised to clarify that the pre-work abstinence period applies to the 5 hours before an individual arrives at the licensee's or other entity's facility for any purpose, except if an individual is called in to perform an unscheduled working tour, as discussed with respect to proposed §26.27(c)(3). This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B.

Proposed §26.27(b)(4)(ii) would retain current §26.20(a)(2).

Proposed §26.27(b)(5) would be added to require the FFD policy to inform individuals that abstinence from alcohol during the 5 hours preceding arrival at a licensee's or other entity's site, as required in proposed §26.27(b)(4), may not be sufficient to ensure that an individual is fit for duty upon reporting to work. Some individuals who have complied with the 5-hour abstinence requirement could have BACs above the cutoff levels specified in proposed §26.103 when they arrive at the licensee's or other entity's facility, depending upon the amount of alcohol and food that the individual consumed before the abstinence period began, body weight, and other factors. This proposed paragraph would be added to meet Goal 7 of this rulemaking with respect to protecting the due process rights of individuals who are subject to alcohol testing under Part 26 by ensuring that they are aware that the required 5-hour abstinence period may be insufficient to assure they have a BAC below the cutoff levels in this part when arriving for work.

Proposed §26.27(b)(6) would amend the last sentence of current §26.20(a), which requires the FFD policy to address other factors that could affect individuals' abilities to perform their duties safely and competently, such as mental stress, fatigue, and illness. The proposed provision would add a requirement for the FFD policy also to address the use of prescription and over-the-counter medications that could cause impairment at work. For example, some licensees or other entities may require individuals to self-report to the FFD program their use of any prescription medications that are labeled with a warning indicating that use of the medication may cause impairment. The licensee's or other entity's FFD policy may require that an individual who is taking a medication that can cause impairment must be temporarily re-assigned to job duties that the individual can perform without posing a risk to the individual or public health and safety while he or she is taking the medication. Therefore, the proposed rule

would require licensees and other entities to include such information in the FFD policy to ensure that individuals are aware of the actions they may be required to take when using these substances, consistent with Goal 7 of this rulemaking with respect to protecting the due process rights of individuals who are subject to the policy. The addition of this requirement would also increase the internal consistency of the rule because other portions of the proposed (and current) rule establish requirements related to using prescription and over-the-counter medications, including, for example, proposed §26.29(a)(6), which would require FFD training to address this topic, and proposed §26.183(j)(2), which would require the MRO to determine whether a non-negative confirmatory drug test result that is due to using a prescription or over-the-counter medication represents substance abuse. Therefore, the proposed requirement for the FFD policy to address the use of prescription and over-the-counter medications that could cause impairment at work would also meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.27(b)(7) would amend current §26.20(b), which requires the FFD policy to describe programs that are available to individuals desiring assistance in dealing with drug, alcohol, or other problems that may adversely affect their performance of their job duties. Proposed §26.27(b)(7) would add fatigue as one of the problems for which individuals may be seeking assistance because sleep disorders (e.g., sleep apnea, insomnia, restless leg syndrome) can substantially affect individuals' abilities to obtain sufficient quality sleep. Poor quality sleep causes fatigue, which may degrade an individual's ability to safely and competently perform his or her duties. Sleep disorders affect a sizeable portion of the U.S. work force. According to polls conducted by the NSF about two-thirds of U.S. adults report experiencing one or more symptoms associated with insomnia, sleep apnea, or restless leg syndrome at least a few nights a week (National Sleep Foundation, 2003) and nearly one out of

five (19 percent) report making occasional or frequent errors due to sleepiness (National Sleep Foundation, 2000). Proposed §26.27(b)(7) would ensure that individuals are aware of the services that are available for diagnosing and treating sleep disorders that can adversely affect their job performance. This proposed change would be made to meet Goal 2 of this rulemaking, which is to strengthen the effectiveness of FFD programs at nuclear power plants by reducing the potential for worker fatigue to adversely affect public health and safety and the common defense and security, through establishing clear and more readily enforceable requirements concerning the management of worker fatigue. In addition, the proposed rule would replace the phrase, "adversely affect the performance of activities within the scope of this part," in the current provision with the phrase, "could adversely affect an individual's ability to safely and competently perform the job duties that require an individual to be subject to this part," for the reasons discussed with respect proposed §26.23(c).

Proposed §26.27(b)(8) would retain the requirement in current §26.20(d) that the FFD policy must specify the consequences of violating the policy. The current requirements in this paragraph that are related to the procedures that the licensee or other entity would implement if an individual violates the FFD policy would be moved to proposed §26.27(c) [Procedures], which addresses FFD program procedures for organizational clarity.

Proposed §26.27(b)(9) would add a requirement for licensees' and other entities' FFD policies to describe the individual's responsibility to report legal actions, as defined in proposed §26.5 [Definitions]. The new requirement to report legal actions is discussed with respect to proposed §26.61 [Self-disclosure and employment history]. However, the proposed rule would require the FFD policy to address the reporting of legal actions to ensure that individuals are aware of it and are not at risk of being subject to sanctions for failing to report any legal actions. This proposed change would be made to meet Goal 7 of this rulemaking with respect to

protecting the due process rights of individuals who are subject to the policy, as discussed in Section IV. B.

Proposed §26.27(b)(10) would add a requirement for the FFD policy to describe the responsibilities of managers, supervisors, and escorts to report FFD concerns. The current rule implies that managers and supervisors have the responsibility to report FFD concerns in §26.22(a)(5), which requires managers and supervisors to be trained in procedures "for initiating appropriate corrective action." Similarly, the last phrase of §26.22(b) requires that escorts be trained in procedures "for reporting problems to supervisory or security personnel," and, therefore, also implies that escorts have a reporting responsibility. However, the current rule does not explicitly state that the FFD policy must convey this requirement. Therefore, the proposed rule would add §26.27(b)(10) to enhance the internal consistency of the rule. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.27(b)(11) would add a requirement for the FFD policy to state that individuals who are subject to the rule must report FFD concerns. The proposed provision would be added for consistency with proposed §26.33 [Behavioral observation], which would require individuals who are subject to the rule to perform behavioral observation and to report an FFD concern if they detect behaviors that may indicate possible use, sale, or possession of illegal drugs; use or possession of alcohol on site or while on duty; or impairment from fatigue or any cause that, if left unattended, may constitute a risk to the health and safety of the public. Proposed §26.29 [Training] would establish a requirement for all individuals who are subject to the rule to be trained in behavioral observation. As a group, these proposed requirements would be added to enhance the effectiveness of Part 26 in assuring the early detection of individuals who are not fit to perform the job duties that require them to be subject to this part,

which is one of the performance objectives that FFD programs must meet, as discussed with respect to current §26.10(b) and proposed §26.23(c). The proposed provision would also be added to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003, as discussed in Section IV. B. The specific requirement for licensees' and other entities' FFD policies to state that individuals must report FFD concerns in proposed §26.27(b)(11) would be necessary to ensure that individuals are aware of their responsibility to report concerns (and that sanctions may be imposed if they do not) to meet Goal 7 of this rulemaking with respect to protecting the due process rights of individuals who are subject to the policy, as discussed in Section IV. B.

Proposed §26.27(c) [Procedures] would combine the requirements related to procedures contained in current §26.20(c)–(e), and would add other requirements, as follows:

Proposed §26.27(c)(1) would retain the requirements in current §26.20(c). The phrase, "privacy and due process rights of an individual," would be added to clarify the requirement for "protecting the employee," contained in current §26.20(c). For example, individuals' privacy rights under the proposed rule include, but are not limited to, requirements for the protection of personal information that is collected about the individual and individual privacy during specimen collections. Examples of individuals' rights to due process under the proposed rule include, but are not limited to, the right to an objective and impartial review of a determination that the individual has violated the FFD policy, the right to advance knowledge of rule provisions and FFD policy requirements that affect the individual, and the right to request testing of a split specimen or retesting an aliquot of a single specimen, if the individual questions a confirmed non-negative test result. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.27(c)(2)(i) and (c)(2)(ii) would divide current §26.20(d) into separate paragraphs that address different topics. Proposed §26.27(c)(2)(i) would retain the requirement for licensees and other entities to have procedures that specify the immediate and followup actions that must be taken if an individual is determined to have been involved in the use, sale, or possession of illegal drugs. Proposed §26.27(c)(2)(ii) would continue to require licensees' and other entities' procedures to specify the immediate and followup actions to be taken if an individual is determined to have consumed alcohol to excess before the mandatory pre-work abstinence period, during the mandatory pre-work abstinence period, or while on duty, as determined by a test that measures BAC. The proposed rule would divide the current paragraph into two paragraphs to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.27(c)(2)(iii) and (c)(2)(iv) would require that licensees and other entities who are subject to the rule must prepare written procedures for implementing the FFD program that address followup actions for attempted subversion of the testing process. Proposed §26.27(c)(2)(iii) would require procedures to specify immediate and followup actions if an individual has attempted to subvert the testing process by adulterating, substituting, or diluting specimens (in vivo or in vitro), or by any other means. Proposed §26.27(c)(2)(iv) would require procedures to address the actions to be taken if an individual has refused to provide a specimen for testing. The proposed rule would add these provisions for consistency with proposed §26.75(b), which would require licensees and other entities to terminate an individual's authorization and, thereafter, permanently deny authorization to any individual who has committed any act or attempted act to subvert the testing process, including refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen, for any test required under this part. Adding the proposed requirements for

procedures to address these circumstances would meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.27(c)(2)(v) would require that the written procedures must address immediate and followup actions for individuals who have had drug- or alcohol-related legal actions taken against them, as defined in proposed §26.5 [Definitions]. The proposed paragraph would support related provisions in proposed §26.69(d) [Maintaining authorization with other potentially disqualifying FFD information], which, in general, require licensees and other entities to take certain steps if an individual has had drug- or alcohol-related legal actions taken against them while they are maintaining authorization to perform the job duties that require them to be subject to this part. Adding the proposed requirement for procedures to address these circumstances would meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, and ensure the internal consistency of the proposed rule.

Proposed §26.27(c)(3) would amend current §26.20(e). The proposed paragraph would continue to require licensees and other entities to have procedures to describe the process that the licensee or other entity will use to ensure that individuals who are called in to perform an unscheduled working tour are fit for duty. The proposed paragraph would also retain the requirement in the last sentence of current §26.20(e)(3) that consumption of alcohol within the 5-hour pre-duty abstinence period may not by itself preclude a licensee or other entity from using individuals who are needed to respond to an emergency. However, this sentence would be moved from the end of the last sentence in the current paragraph to the introductory paragraph of proposed §26.27(c)(3) because it applies generally to the topic of this proposed paragraph, rather than only to the topic addressed in current §26.20(e)(3). This proposed

change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, as discussed in Section IV. B.

The proposed rule also would retain the other requirements of current §26.20(e), as follows: Proposed §26.27(c)(3)(i) would retain current §26.20(e)(1), which requires the individual who is called in to state whether the individual considers himself or herself fit for duty and whether he or she has consumed alcohol within the pre-duty abstinence period stated in the FFD policy. Proposed §26.27(c)(3)(ii)(A) and (c)(3)(ii)(B) would retain current §26.20(e)(2) and the first sentence of current §26.20(e)(3), which require that an individual who reports that he or she has used alcohol and is called in must be subject to alcohol testing, and that the licensee or other entity must establish controls and conditions under which an individual who has consumed alcohol may perform work safely.

The proposed rule would also add a requirement to proposed §26.27(c)(3)(i) and (c)(3)(iii). The proposed rule would require an individual who is called in to state whether he or she considers himself or herself to be fit for duty, in addition to stating whether he or she has consumed alcohol. The proposed rule would add this requirement to recognize that there are conditions other than the consumption of alcohol that may cause an individual to be unable to safely and competently perform duties, including, but not limited to, fatigue (as discussed with respect to Subpart I [Managing Fatigue]). Therefore, requiring individuals to report other conditions that may cause them to be impaired when called in to perform an unscheduled working tour, under proposed §26.27(c)(3)(i), would strengthen the effectiveness of FFD programs by providing the licensee or other entity with more complete information about the individual's condition to determine whether there is a need to establish controls and conditions under which the individual may safely perform work, as required under proposed

§26.27(c)(3)(iii). These proposed changes would be made to meet Goal 3 of this rulemaking, which is improve the effectiveness and efficiency of FFD programs.

Proposed §26.27(c)(3)(ii)(C) would be added to clarify that licensees and other entities may not impose sanctions if an individual is called in for an unscheduled working tour and has consumed alcohol during the pre-duty abstinence period specified in the FFD policy. During the public meetings discussed in Section V, the stakeholders requested this clarification to ensure that, if an individual who is called in unexpectedly has a confirmed positive test result for alcohol, he or she would not be subject to the sanctions that are otherwise required under this part for a confirmed positive alcohol test result. The NRC concurs with this recommendation because sanctions for the consumption of alcohol in these circumstances would be inappropriate, given that the individual would have been unaware that he or she would be called in to work. The proposed revision also would be consistent with the original intent of the rule. Therefore, the proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.27(c)(4) would be added to require that FFD procedures must describe the process to be followed when another individual's behavior raises an FFD concern and for reporting the concern. As discussed with respect to proposed §26.27(b)(11), this proposed paragraph would be added for consistency with proposed §26.33 [Behavioral observation], which would establish a new requirement that all individuals who are subject to the rule must perform behavioral observation and report any FFD concerns, and proposed §26.29 [Training], which requires that individuals who are subject to this part must be trained to perform behavioral observation. The proposed requirement would be added to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs, and Goal 4, which is to improve consistency between FFD requirements and access authorization

requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Proposed §26.27(d) would retain the requirements of current §26.20(f).

Section 26.29 Training

Proposed §26.29 [Training] would combine and amend current §26.21 [Policy communications and awareness training] and §26.22 [Training of supervisors and escorts]. The proposed section would require that all individuals who are subject to the rule must receive the same training, to include, for example, behavioral observation, whereas current §26.22 requires that only supervisors and escorts must receive behavioral observation training. Increasing the number of individuals who are trained in behavioral observation would enhance the effectiveness of FFD programs by increasing the likelihood of detecting potential impairment, consistent with Goal 3 of this rulemaking, as discussed in Section IV. B.

Proposed §26.29(a) [Training content] would combine the training topics listed in current §§26.21(a)(1)–(a)(5), 26.22(a)(1)–(a)(5), and 26.22(b). The required training topics would be rewritten in terms of knowledge and abilities (KAs) to be consistent with terminology used by licensees and other entities in other required training programs to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.29(a)(1) would combine current §26.21(a)(1) with the latter portion of current §26.21(a)(5). Consistent with the current training requirements, the proposed paragraph would require licensees and other entities to ensure that individuals who are subject to the FFD policy have knowledge of the FFD policy and procedures that apply to them, the

methods used to implement the policy and procedures, and the consequences of violating the policy and procedures.

Proposed §26.29(a)(2) would retain the requirement in current §26.22(a)(1) that licensees and other entities who are subject to the rule must ensure that individuals understand their roles and responsibilities under the FFD program, such as avoiding substance abuse and reporting for testing within the time limit specified in FFD program procedures.

Proposed §26.29(a)(3) would amend the terminology used in current §26.22(a)(2), which requires FFD training to address the roles and responsibilities of others, such as the personnel, medical, and employee assistance program (EAP) staffs. The proposed paragraph would replace the references to the "personnel" function and "medical" staff in current §26.22(a)(2) with "human resources" and ""FFD" staff, respectively. The proposed rule would also move the reference to the MRO into this paragraph from current §26.21(a)(3). These proposed changes would be made to update the terminology in this paragraph to be consistent with other terms used throughout the regulation to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.29(a)(4) and (a)(5) would amend current §26.21(a)(4) and (a)(2), respectively, by changing some of the language used in the current provisions. Current §26.29(a)(4) requires FFD training to inform individuals who are subject to the rule of any EAPs that are available to them. The proposed rule would eliminate the reference to EAPs "provided by the licensee" in the current provision and amend it as "EAP services available to the individual" because there are other entities who would be subject to this requirement under the proposed rule. Proposed §26.29(a)(5) would amend current §26.21(a)(2) by replacing the phrase, "abuse of drugs and misuse of alcohol," with "abuse of illegal and legal drugs and alcohol" for greater accuracy in describing the required knowledge. These proposed changes

would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

Proposed §26.29(a)(6) would retain the portion of current §26.21(a)(3) which requires licensees to ensure that individuals understand the effects of prescription and over-the-counter drugs and dietary factors on job performance. The proposed rule would add a requirement for FFD training to address the effects of illness, mental stress, and fatigue on job performance, in order to ensure that individuals understand the bases for the licensee's or other entity's FFD policy regarding these conditions. The requirement in the last sentence of current §26.20(a) for the FFD policy to address these factors would be moved to proposed §26.27(b)(6) because proposed §26.27(b) would address FFD policy requirements. These proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.29(a)(7) would retain the portion of current §26.21(a)(3) that requires licensees and other entities to ensure that individuals who are subject to the rule understand the effects of prescription and over-the-counter drugs and dietary factors on drug and alcohol test results. Examples of medications, supplements, and dietary factors that can affect drug and alcohol test results may include, but are not limited to, ingesting foods containing poppy seeds, drinking coca tea, using some liquid or inhalant cold and cough preparations containing alcohol or codeine, and taking supplements containing hemp oil.

Proposed §26.29(a)(8) and (a)(9) would retain the requirements in current §26.22(a)(3) and (a)(4), respectively.

Proposed §26.29(a)(10) would amend current §26.22(a)(5). The proposed provision would retain the current requirement for FFD training to address the licensee's or other entity's process for initiating appropriate corrective action if an individual has an FFD concern about

another person, to include referral to the EAP. The proposed rule would add a requirement for FFD training to ensure that individuals understand their responsibility to report FFD concerns to the person(s) who are designated in FFD program procedures to receive such reports. This proposed change would be made for consistency with proposed §26.33 [Behavioral observation], which would require individuals to perform behavioral observation and report any FFD concerns, as discussed with respect to proposed §26.27(b)(11), and proposed §26.27(c)(4), which would require procedures for implementing the requirement. This group of inter-related proposed requirements would be added to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs, and Goal 4 of this rulemaking, which is to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

A new §26.29(b) [Comprehensive examination] would require that individuals who are subject to the FFD program must demonstrate attainment of the KAs specified in proposed §26.29(a) by passing a comprehensive examination. This new requirement would be added because there have been several instances since Part 26 was first promulgated in which individuals were able to overturn determinations that they had violated a licensee's FFD policy on the basis that they had not understood the information they received during FFD training and so could not be expected to comply with the requirements of the policy. Therefore, the proposed rule would require individuals to demonstrate their attainment of the KAs listed in proposed §26.29(a) to ensure that the FFD training has been effective. The proposed rule would also require remedial training for those who fail to achieve a passing score on the examination. Proposed §26.29(b) would require the examination to include at least one question for each KA, and establish a minimum passing score of 80 percent. These proposed

requirements would be modeled on other required training programs that have been successful in ensuring that examinations are valid and individuals have achieved an adequate understanding of the subject matter. The proposed paragraph would be added to meet the portion of Goal 3 of this rulemaking that relates to improving the effectiveness of FFD programs by establishing a method to ensure that individuals understand the requirements with which they must comply.

The proposed paragraph also would permit the use of various media for administering the comprehensive examination, in order to achieve the efficiencies associated with computer-based training and testing, for example, and other new training delivery technologies that may become available. Permitting the use of various media to administer the examination would meet the portion of Goal 3 of this rulemaking that relates to improving the efficiency of FFD programs. The proposed permission would also meet Goal 5, which is to improve Part 26 by eliminating or modifying unnecessary requirements, by providing flexibility in the methods that licensees and other entities may use to administer the required examination.

Proposed §26.29(c) [Training administration] would combine and amend the portions of current §26.21(b) and §26.22(c) that require FFD training for individuals, supervisors, and escorts before they are permitted to perform duties that require them to be subject to this part.

Proposed §26.29(c)(1) would require that all personnel who are subject to this part must complete FFD training before the licensee or other entity grants initial authorization to the individual, as defined in proposed §26.55 [Initial authorization]. The proposed rule would also require that an individual's training must be current before the licensee or other entity grants an authorization update or reinstatement to the individual, as defined in proposed §26.57 [Authorization update] and §26.59 [Authorization reinstatement], respectively. The proposed paragraph also would eliminate the requirement to upgrade training for newly assigned

supervisors within 3 months of a supervisory assignment in current §26.22(c), because all personnel would receive the same training and be required to complete the training before a licensee or other entity grants authorization to any individual. The proposed changes would be made for consistency with the new requirements related to granting and maintaining authorization that would be established in proposed Subpart C [Granting and Maintaining Authorization], as discussed with respect to that subpart.

Proposed §26.29(c)(2) would retain but combine the requirements for annual refresher training in current §26.21(b), which addresses individuals who are subject to this part, and §26.22(c), which addresses supervisors and escorts. The current requirements would be combined because all personnel would receive the same training under the proposed rule. The proposed paragraph would also permit individuals who pass a comprehensive "challenge" examination that demonstrates their continued understanding of the FFD program requirements to be excused from the refresher training that would otherwise be required under the proposed paragraph. The challenge examination would be required to meet the examination requirements specified in proposed §26.29(b) [Comprehensive examination] and individuals who did not pass would undergo remedial training. Permitting individuals to pass a comprehension examination rather than take refresher training each year would ensure that they are retaining their FFD knowledge and abilities while reducing some costs associated with meeting the annual refresher training requirement. Therefore, this proposed change would meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Proposed §26.29(c)(3) would permit licensees and other entities to use various media, in addition to traditional classroom instruction, for presenting initial and refresher training for the same reasons discussed with respect to the portion of proposed §26.29(b) [Comprehensive

examination] that would permit licensees and other entities to use various media to administer the comprehensive examination. The proposed requirements for a licensee or other entity to monitor the completion of training and provide access to an instructor or subject matter expert should ensure that individuals who are trained using different media would achieve the same understanding as persons who are trained in a classroom setting with an instructor present. This proposed flexibility may reduce the costs associated with presenting initial and refresher training only in a classroom setting. Therefore, this proposed change would meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

To meet the annual refresher training requirement for individuals, proposed §26.29(d) [Acceptance of training] would permit licensees and other entities to accept FFD training that was provided by other licensees and entities who are subject to the rule. Licensees and other entities would also be permitted to accept a passing result from a comprehensive examination that was administered by another Part 26 FFD program in lieu of refresher training, if the examination meets the requirements of proposed §26.29(b) [Comprehensive examination]. Proposed §26.29(c)(4) would incorporate item 3.3 of NUREG-1385, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions," which recommends acceptance of prior training. The proposed provision would also meet Goal 4 of this rulemaking, which is to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. These access authorization requirements also permit licensees and other entities to rely on training and examinations administered by other Part 26 programs.

Section 26.31 Drug and alcohol testing

Proposed §26.31 [Drug and alcohol testing] would rename current §26.24 [Chemical and alcohol testing]. The proposed rule, in general, would replace the phrase, “chemical testing,” with the term, “drug testing,” because the testing for chemicals that is required in the rule is performed only in the context of urine drug testing. Therefore, the term, “drug testing,” more accurately conveys the nature of the testing that is performed. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.31(a) [General] would retain but update the language in current §26.24(a) to be consistent with the new terminology used throughout the rule, as discussed in proposed §26.5 [Definitions]. For example, the proposed rule would replace “licensee” with “licensees and other entities” to refer to the entities who are subject to the rule. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

Proposed §26.31(b) [Assuring the honesty and integrity of FFD program personnel] would amend current Section 2.3 in Appendix A to Part 26, as explained below.

Proposed §26.31(b)(1) would amend the first paragraph of current Section 2.3 in Appendix A to Part 26, which requires licensees to carefully select and monitor persons responsible for administering the testing program to assure they meet the highest standards of honesty and integrity. The proposed rule would replace the current list of individuals who would be subject to this requirement with a cross-reference to §26.25(a)(4) of the proposed rule, which specifies, in detail, the FFD program personnel who must be subject to the FFD program. This cross-reference would be added to avoid repeating the list of personnel in this paragraph.

The proposed paragraph would also add a reference to factors, other than a personal relationship with an individual who is subject to testing, that have the potential to cause an individual to be subject to influence attempts or may adversely affect the honesty and integrity of FFD program personnel. In addition to a personal relationship with an individual who is subject to testing, factors that could cause an individual to be compromised may include, but would not be limited to, a substance abuse problem [as discussed with respect to proposed §26.25(a)(4)] or financial problems. Therefore, the proposed rule would add a reference to these additional factors to more accurately characterize the scope of potential concerns that licensees and other entities must consider when selecting and monitoring the honesty and integrity of FFD program personnel. The proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

Proposed §26.31(b)(1)(i) would amend current Section 2.3(2) in Appendix A to Part 26 in response to implementation questions regarding the current requirements that the NRC staff has received since Part 26 was first promulgated as well as discussions with stakeholders during the public meetings discussed in Section V. In response to numerous questions from licensees, the proposed paragraph would clarify that the background investigations, credit and criminal history checks, and psychological evaluations that are required for persons who are granted unescorted access to protected areas in nuclear power plants are acceptable when determining the honesty and integrity of FFD program personnel. The proposed rule would retain the term, “appropriate,” in the current rule for two reasons. First, it would be used to indicate that, for FFD program personnel who are employed by entities who are subject to the rule but are not nuclear power plants, the requirements may be met through investigations, checks, and evaluations that provide the information needed to determine the honesty and integrity of FFD program personnel but may differ from those required under nuclear power

plant access authorization programs. In addition, the proposed rule would retain the term, “appropriate,” because it has particular relevance to the requirement for licensees and other entities to conduct criminal history checks for FFD program personnel. In some cases, licensees and other entities cannot legally obtain the same type of criminal history information about FFD program personnel as they are able to obtain for other individuals who are subject to Part 26. Therefore, the term, “appropriate,” would be used to indicate that local criminal history checks for FFD program personnel who do not have unescorted access to nuclear power plant protected areas are acceptable. These proposed changes would be made to meet the portion of Goal 6 of this rulemaking that pertains to improving clarity in the language of the rule.

The requirement in current Section 2.3(2) in Appendix A to Part 26 for "appropriate background checks and psychological evaluations" to be "conducted at least once every three years" would be relaxed to require that credit and criminal history checks and updated psychological assessments be conducted nominally every 5 years. The proposed rule would relax the current requirement for several reasons. First, the NRC is not aware of any instances in which licensees and other entities have identified new information about FFD program personnel from updating the background checks and psychological assessments that had not already been identified through other avenues, including self-reports by FFD program personnel, drug and alcohol testing, and behavioral observation. However, the NRC continues to believe that the required updates provide an independent method to verify the ongoing honesty and integrity of FFD program personnel that is necessary because of the critical importance of FFD program personnel in assuring program effectiveness. Therefore, the proposed rule would retain the current requirement for updated background checks and psychological assessments but would reduce the required frequency of these updates from every 3 years to every 5 years. This proposed change would be made to meet Goal 5 of this

rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements. In addition, the proposed frequency for these updates would increase the consistency of Part 26 with access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003, which is Goal 4 of this rulemaking.

Proposed §26.31(b)(1)(ii) would amend current Section 2.3(1) in Appendix A to Part 26 for clarification in response to the many implementation questions that have arisen since the regulation was published. In the current rule, individuals who have a personal relationship with the individual being tested (i.e., a donor), such as the donor's "supervisors, coworkers, and relatives," are prohibited from performing any "collection, assessment, or evaluation procedures" involving the individual being tested. The restriction on "supervisors, coworkers, and relatives" was included in the current rule to provide examples of the "personal relationships" referenced in the introductory paragraph of current Section 2.3 in Appendix A to Part 26. The restriction on coworkers in the current rule has been misinterpreted by some licensees as meaning that no one who is an employee of the same corporation may be involved in collection, assessment, or evaluation procedures. However, in a large corporation, there will be many individuals who are employed by the same corporation who do not have personal relationships with FFD program personnel, specifically, or with other individuals who are subject to testing, in general. Therefore, in proposed §26.31(b)(1)(ii), the phrase, "in the same work group," would be added to clarify that the example regarding coworkers pertains to individuals who report to the same manager. For example, FFD program personnel report to the FFD program manager and so would be considered "coworkers in the same work group" to whom the proposed restriction would apply. In addition, the proposed paragraph would add a reference to determinations of fitness (discussed with respect to proposed §26.189

[Determination of fitness]) to provide a clarifying example of the assessment and evaluation procedures that FFD program personnel would be prohibited from performing if the FFD program staff member has a personal relationship with the subject individual. These proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.31(b)(1)(iii) would relax the prohibition on individuals who have "personal relationships" with the donor from performing specimen collection procedures in current Section 2.3(1) in Appendix A to Part 26 in response to stakeholder requests during the public meetings discussed in Section V. With respect to specimen collections, stakeholders were convincing that the current restriction imposes an unnecessary burden when the objective of ensuring the integrity of specimen collections in these circumstances could be achieved by other means. Therefore, in proposed §26.31(b)(1)(iii), individuals who have a personal relationship with a donor would be permitted to collect specimens, if the collection and preparation of the specimens for shipping is monitored by another individual who does not have a personal relationship with the donor and is not a supervisor, a coworker in the same work group, or a relative of the donor. The proposed rule would require that the independent individual who is designated to monitor the collection must be trained to monitor specimen collections. The proposed paragraph would also provide examples of the types of individuals who may monitor the integrity of specimen collection procedures in these circumstances, including but not limited to, security force or quality assurance personnel. This proposed change would be made to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements, by permitting monitored collections in these circumstances while continuing to assure the integrity of specimen collections from FFD program personnel. The proposed rule would retain the prohibition on individuals who have

personal relationships with the donor from performing assessment and evaluation procedures because monitoring of these activities by qualified, independent personnel would not be feasible.

Proposed §26.31(b)(1)(iv) would be added to prohibit a collector who has a personal relationship with the donor from acting as a urine collector under monitoring, if a directly observed collection is required. This proposed prohibition would be necessary to minimize embarrassment to the donor (and the collector) during a directly observed collection. The proposed paragraph would be added to meet Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Proposed §26.31(b)(1)(v) would amend current Section 2.3(3) in Appendix A to Part 26 to require that MROs who are on site at a licensee's or other entity's facility must be subject to behavioral observation. For the purposes of the proposed paragraph, a "facility" would include, but is not limited to, a licensee's or other entity's corporate offices and any medical facilities that are operated by the licensee or other entity. The proposed requirement would be added because MROs are "persons responsible for administering the testing program," but some FFD programs have not included MROs in the behavioral observation element of their programs. However, the proposed rule would limit the behavioral observation of MROs to those times when they are on site at a licensee's or other entity's facility, in order to permit licensees and other entities to continue relying on the services of MROs who normally work independently, often alone, in offices at a geographical distance from the licensee's or other entity's facilities so that behavioral observation is impractical. Limiting the proposed requirement for behavioral observation of MROs to those instances in which the MRO is working at a licensee's or other entity's facility would be adequate to assure the continuing honesty and integrity of these MROs because MROs who work off site would not be interacting on a daily basis with other individuals

who are subject to the FFD program. Therefore, off-site MROs would be less likely to be subject to potential influence attempts than MROs who normally work on site because they are generally inaccessible. Further, the proposed rule would continue to require all MROs to be subject to the other FFD program elements that are required in this proposed Subpart, including drug and alcohol testing and regular psychological assessments and background investigations, which would permit licensees and other entities to monitor off-site MROs' honesty and integrity. This proposed relaxation would be added to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Proposed §26.31(b)(2) would provide another relaxation related to collecting specimens from FFD program personnel. The proposed paragraph would permit FFD program personnel to submit specimens for testing at collection sites that meet the requirements of 49 CFR Part 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs" (65 FR 41944; August 9, 2001). As discussed with respect to proposed §26.31(b)(1), some FFD program personnel, such as contract MROs and EAP staff members, normally work at locations that are so distant from a licensee's collection site(s) as to make it impractical for them to be randomly tested at a licensee's or other entity's collection site. Permitting these FFD program personnel to be tested at local collection sites that follow similar procedures would be adequate to meet the goal of ensuring their continuing honesty and integrity. Therefore, the proposed paragraph would be added to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Proposed §26.31(c) [Conditions for testing] would replace current §26.24(a)(1)–(a)(4). The proposed paragraph would list the situations in which testing is required in separate paragraphs, such as "pre-access," "for cause," and "post-event" testing, to clarify that each situation for which testing is required stands on its own. The current provision in §26.24(a)(3),

in particular, has led to confusion and misinterpretation of the regulations, to be corrected as noted below. Specific requirements for conducting the testing would be addressed in proposed Subparts E [Collecting Specimens for Testing], F [Licensee Testing Facilities], and G [Laboratories Certified by the Department of Health and Human Services]. The proposed rule would reorganize and amend current §26.24(a)(1)–(a)(4) to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.31(c)(1) [Pre-access] would amend current §26.24(a)(1), which requires pre-access testing within 60 days before the initial granting of unescorted access to protected areas or assignment to job duties within the scope of this part. The proposed paragraph would introduce the concepts of "initial authorization," "authorization update," and "authorization reinstatement," which refer to categories of requirements that licensees and other entities must meet in order to assign an individual to job duties which require the individual to be subject to Part 26. Section 26.65 [Pre-access drug and alcohol testing] in Subpart C [Granting and Maintaining Authorization] of the proposed rule would specify detailed requirements for conducting pre-access testing.

Proposed §26.31(c)(2) [For cause] and §26.31(c)(3) [Post event] would clarify and amend current §26.24(a)(3), as follows:

Proposed §26.31(c)(2) [For cause] would continue to require for-cause testing in response to any observed behavior or physical condition indicating possible substance abuse. The proposed rule would also retain the current requirement for testing if the licensee or other entity receives credible information that an individual is engaging in substance abuse. The term, "substance abuse," would be defined in proposed §26.3 [Definitions].

Proposed §26.31(c)(3) [Post event] would amend the portion of current §26.24(a)(3) that requires drug and alcohol testing when an event involving a failure in individual performance

leads to significant consequences. The proposed rule would amend the current provision because it has been subject to misinterpretation and numerous questions from licensees.

The phrase, “if there is reasonable suspicion that the worker’s behavior contributed to the event,” in current §26.24(a)(3) has been subject to misinterpretation. The location of this phrase at the end of the list of conditions under which post-event testing must be performed has led some licensees to conclude that this phrase applies only to events involving actual or potential substantial degradations of the level of safety of the plant. Other licensees have misinterpreted the term, “reasonable suspicion” as meaning, “reasonable suspicion of substance abuse,” or some other “illegal” or “disreputable” activity. Neither of these interpretations is consistent the intent of this paragraph. Therefore, to clarify the intent of the provision, the proposed rule would eliminate the phrase, “if there is reasonable suspicion that the worker’s behavior contributed to the event,” from the end of the list of significant events that require post-event testing and, instead, require post-event testing as soon as practical after significant events [as listed in proposed §26.31(c)(3)(i)–(c)(3)(iii)] involving a human error that may have caused or contributed to the event. The proposed rule would use the term, “human error,” rather than the current term, “worker’s behavior,” to emphasize that post-event testing would be required for acts that unintentionally deviated from what was planned or expected in a given task environment (NUREG/CR-6751, “The Human Performance Evaluation Process: A Resource for Reviewing the Identification and Resolution of Human Performance Problems”) as well as failures to act (i.e., errors of omission). Therefore, testing would be required regardless of whether there was “reasonable suspicion” that the individual was abusing drugs or alcohol for the consequences listed in the proposed paragraph.

In addition, the second sentence of proposed §26.31(c)(3) would be added in response to stakeholder comments at the public meetings discussed in Section V. The stakeholders

noted that the current provision does not clearly delineate the scope of individuals who must be subject to post-event testing. Some licensees have misinterpreted the current provision as requiring that all individuals who are involved in a significant event must be tested, including individuals whose behavior played no causal or contributing role in the event. For example, these licensees' FFD programs would require that an individual who was exposed to radiation in excess of regulatory limits must be tested, even if other individuals' actions (or failures to act) were responsible for the event and the individual who suffered the exposure was a bystander. Therefore, the second sentence of the proposed provision would clarify the original intent of this paragraph by stating that only the individual(s) who committed the error(s) would be subject to post-event testing.

Proposed §26.31(c)(3)(i) would provide a threshold for the types of workplace personal injuries and illnesses for which post-event testing would be required in response to implementation questions related to current §26.24(a)(3). Some licensees have misinterpreted the current provision as requiring post-event testing for any personal injury, no matter how minor. The proposed paragraph would clarify the type of personal injuries and illnesses for which post-event testing would be required by establishing a threshold that is based on the general criteria contained in 29 CFR 1904.7 of the regulations of the Occupational Safety and Health Administration (OSHA) for recording occupational injuries and illnesses. As defined in the OSHA standard and the proposed rule, these would include any injuries and illnesses which result in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, loss of consciousness, or other significant injury or illness as diagnosed by a physician or other licensed health care professional, even if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness. The proposed rule would add this clarification to reduce the number of

unnecessary post-event tests performed for minor injuries and illnesses and meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

In response to stakeholder comments at the public meetings discussed in Section V, proposed §26.31(c)(3)(i) would also include the qualifying phrase, "within 4 hours after the event," with reference to the recordable personal injuries and illnesses that would trigger post-event testing. The stakeholders noted that, in some cases, it is difficult to detect illnesses and injuries that meet the proposed threshold for post-event testing at the time they occur. For example, if an individual has been injured on site but does not report the injury to the licensee or other entity and waits for several days to seek treatment from his or her private physician, the licensee or other entity may not learn of the injury. The extent of an injury may be unclear at the time it occurs and so it may appear to fall below the threshold for post-event testing until several days have passed. In these examples, if the licensee or other entity learns after several days that the injury would have met the threshold for post-event testing, it would be too late for post-event testing to be of any value in determining whether the individual's use of drugs or alcohol may have contributed to the event. If alcohol or drug use had contributed to the event, testing several days later would be unlikely to detect it because of the effects of metabolism. Further, it would be difficult to prove that any non-negative test results reflected the individual's condition at the time the event occurred rather than subsequent drug or alcohol use. Therefore, the proposed rule would limit post-event testing to situations in which the licensee or other entity can determine that an injury or illness meets the proposed threshold within 4 hours after the event has occurred, and can conduct the testing within a time frame that will provide useful information about the individual's condition at the time of the event. However, the proposed paragraph should not be misinterpreted as requiring post-event testing to be completed within 4 hours after the event. The time period after the event within which testing must be completed

would be defined in proposed §26.31(c)(3) as “as soon as practical.” This proposed change would be made to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

Proposed §26.31(c)(3)(ii) would carry over the relevant language in the corresponding portion of current §26.24(a)(3), without change.

Proposed §26.31(c)(3)(iii) would carry over the relevant language in the corresponding portion of current §26.24(a)(3), but, as discussed with respect to proposed §26.31(c)(3), would eliminate the current qualifying phrase, “if there is reasonable suspicion that the worker’s behavior contributed to the event.”

Proposed §26.31(c)(4) [Followup] would retain the intent of current §26.24(a)(4) but amend its language. The proposed rule would eliminate the phrase, “to verify continued abstention from the use of substances covered under this part,” because it could be misinterpreted as limiting the substances for which followup testing would be permitted to only those listed in proposed §26.31(d)(1) [Substances tested]. The proposed rule would revise this phrase as, “to verify continued abstinence from substance abuse,” to clarify that FFD programs would be permitted to conduct followup testing for any substances an individual may have abused, subject to certain additional requirements discussed with respect to proposed §26.31(d)(1)(i). Detailed requirements for conducting followup testing would be established in proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information], where they would apply to licensees’ and other entities’ processes for granting and maintaining authorization. The proposed rule would make these changes to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.31(c)(5) [Random] would simplify current §26.24(a)(2) to define random testing as one of the conditions under which testing is required. The detailed requirements for

implementing random testing that are contained in current §26.24(a)(2) would be moved to proposed §26.31(d) [General requirements for drug and alcohol testing]. The proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.31(d) [General requirements for drug and alcohol testing] would be added to better organize requirements related to the general administration of drug and alcohol testing. The proposed rule would present more detailed requirements for conducting drug and alcohol testing in proposed Subparts E [Collecting Specimens for Testing], F [Licensee Testing Facilities], and G [Laboratories Certified by the Department of Health and Human Services]. The proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.31(d)(1) [Substances tested] would retain the list of drugs for which testing must be conducted in current Section 2.1(a) in Appendix A to Part 26, but would clarify that, for some drugs, the testing is conducted to detect drug metabolites. The circumstances in which testing for these substances must be performed (i.e., pre-access, post-event, random) would be moved to proposed §26.31(c) for organizational clarity. In addition, the proposed paragraph would add adulterants to the list of substances for which testing must be conducted, consistent with the addition of specimen validity testing requirements to the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.31(d)(1)(i) would retain the permission in the second sentence of current §26.24(c) for licensees and other entities to consult with local law enforcement agencies or other sources of information to identify drugs that may be abused by individuals in the geographical locale of the FFD program.

Proposed §26.31(d)(1)(i)(A) would retain the permission in current §26.24(c) for licensees and other entities to add to the panel of drugs for which testing is required in proposed §26.31(d)(1). Additional drugs may include, but are not limited to, "designer drugs," such as ecstasy or ketamine, and illegal drugs that are popular in some geographical areas, such as lysergic acid diethylamide-25 (LSD). The proposed paragraph would also require that any additional drugs must be listed on Schedules I–V of section 202 of the Controlled Substances Act [21 U.S.C. 812], which would be consistent with the definition of "illegal drugs" in current §26.3 [Definitions].

Proposed §26.31(d)(1)(i)(B) would retain the last sentence in current §26.24(c), which requires licensees and other entities who are subject to the rule to establish appropriate cutoff levels for any additional substances for which testing will be conducted.

Proposed §26.31(d)(1)(i)(C) would retain the requirement in current Section 2.1(c) in Appendix A to Part 26, which requires licensees and other entities to establish rigorous testing procedures for any additional drugs.

Proposed §26.31(d)(1)(i)(D) would be added to further clarify the requirement in proposed §26.31(d)(1)(i)(C) for "rigorous testing procedures" and would replace the portion of current Section 1.1(2) in Appendix A to Part 26 that requires licensees to obtain written approval from the NRC to test for additional drugs. The purpose of the current requirement is to provide an opportunity for the NRC to verify that the assays and cutoff levels licensees use in testing for additional drugs are scientifically sound and legally defensible. However, the current requirement also imposes a reporting burden. The proposed provision would eliminate this reporting requirement and replace it with requirements for an independent forensic toxicologist to conduct the review that the NRC currently performs. The proposed rule would require the independent forensic toxicologist to certify, in advance and in writing, that the assay to be used

in testing for any additional drugs or drug metabolites, and the cutoff levels to be applied, are scientifically sound and legally defensible. The proposed paragraph would also specify the required qualifications for the forensic toxicologist. Certification of the assay and cutoff levels would not be required in two circumstances: (1) if the HHS Guidelines are revised to permit use of the assay and the cutoff levels in Federal workplace drug testing programs, and (2) if the licensee or other entity has received written approval from the NRC to test for the additional drugs or metabolites and to apply the cutoff levels to be used in testing for the additional drugs or metabolites, as required in current Section 1.1(2) in Appendix A to Part 26. Certification would be unnecessary in these two circumstances because it would be redundant. This proposed change would be made to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements, while continuing to ensure that any drug testing conducted under Part 26 is scientifically sound and legally defensible.

Proposed §26.31(d)(1)(ii) would amend current Section 2.1(b) in Appendix A to Part 26 and would permit licensees and other entities, when conducting for-cause, post-event, and followup testing, to test for any drugs listed on Schedules I–V of the CSA that the licensee or other entity suspects the individual may have abused, as follows:

The proposed paragraph would add a reference to post-event testing for consistency with the intent of current Section 2.1(b) in Appendix A to Part 26, which permits testing for any illegal drugs during a for-cause test. The current rule includes post-event testing within the definition of for-cause testing whereas the proposed rule would use a distinct term, “post-event” testing, to refer to the testing that is required following certain events, as discussed with respect to proposed §26.31(d)(3). Therefore, it would be necessary to add a reference to post-event testing to this paragraph to retain the full intent of the current provision.

The proposed paragraph would also add a reference to followup testing, which would permit the licensee or other entity to test for an additional drug if an individual who is subject to followup testing is suspected of having abused it. For example, if an SAE, in the course of performing a determination of fitness under proposed §26.189 [Determination of fitness], found that an individual was abusing barbiturates, this provision would permit followup testing to verify that the individual is abstaining from such abuse. This proposed change would be made to strengthen the followup testing element of FFD programs by ensuring that followup testing would detect continued drug abuse and would therefore, meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

The proposed paragraph would retain the limitation in current Section 2.1(b) in Appendix A to Part 26, which permits testing only for illegal drugs that the individual is suspected of having abused, and extend that limitation to followup testing. The proposed rule would extend this limitation to followup testing to protect donors' rights to privacy, which is the same reason that the limitation was established in the current rule with respect to for-cause testing. That is, licensees and other entities would be prohibited from conducting a wide spectrum of tests for any drugs without suspicion that the individual had abused them, because such tests could reveal personal medical information about the individual that is irrelevant to the performance objectives of this part, as discussed with respect to §26.23 [Performance objectives]. Thus, extending the current limitation on for-cause testing to followup testing would meet Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

The proposed paragraph would replace the term, "illegal drugs," in current Section 2.1(b) in Appendix A to Part 26 with a specific reference to the drugs that are listed on Schedules I–V of the CSA. These schedules list drugs with abuse potential and include many

drugs with legitimate medical uses that are not “illegal” when used in accordance with a valid prescription for medical purposes. Therefore, replacing the term, “illegal drugs,” with the reference to Schedules I–V of the CSA would more accurately characterize the specific drugs for which testing is permitted. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

Proposed §26.31(d)(1)(ii) would also apply the new requirements in proposed §26.31(d)(1)(i)(D) related to testing for drugs that are not included in the FFD program’s panel of drugs to for-cause, post-event, and followup testing. The proposed paragraph would require the assays and cutoff levels to be used in testing for the additional drugs to be certified by a forensic toxicologist in accordance with proposed §26.31(d)(1)(i)(D). The proposed provision would provide consistency with proposed §26.31(d)(1)(i)(D) and ensure that the testing would be scientifically sound and legally defensible. The proposed change would be made to protect donors’ rights to due process, as it relates to minimizing the possibility of false positive test results, and strengthen the effectiveness of FFD programs by ensuring that tests for additional drugs that are conducted for cause, post-event, or as part of a followup program will accurately detect drugs that an individual may have abused. Therefore, this proposed change would be made to meet Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26, and Goal 3, which is to improve the effectiveness and efficiency of FFD programs.

The last sentence of proposed §26.31(d)(1)(ii) would be added to prohibit inappropriate practices that some FFD programs have implemented. The NRC is aware that some FFD programs have directed their HHS-certified laboratories to test specimens that are collected for for-cause, post-event, or followup testing at the assay’s LOD without first subjecting the specimens to initial testing. In addition, if a drug or drug metabolite is detected at the LOD, the

MROs in these programs have confirmed the test result as an FFD policy violation, despite the quantitative test result falling below the FFD program's established confirmatory cutoff level. Although these practices may increase the likelihood of detecting drug abuse, they are inconsistent with one of the bases for establishing cutoff levels for drug testing in the rule, which is to minimize the likelihood of false positives that could result in the imposition of sanctions on an individual who has not abused drugs. It also subjects individuals who are undergoing for-cause, post-event, or followup testing to unequal treatment when compared to individuals who are subject to random and pre-access testing, in which the established cutoff levels must be applied. Therefore, the proposed rule would specifically prohibit these practices to meet Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26, by requiring that individuals who are subject to for-cause, post-event, and followup testing must be subject to the same testing procedures and cutoff levels as others who are tested under this part.

Proposed §26.31(d)(2) [Random testing] would reorganize and amend the requirements for conducting random testing, which currently appear in §26.24(a)(2), as follows:

Proposed §26.31(d)(2)(i) would add a new requirement for licensees and other entities to administer random testing in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected. This proposed provision would be added because the NRC is aware of instances in which individuals who believed they would have a non-negative result, if tested, have been able to determine the days on which collections were being conducted, which then gave them the opportunity to leave work under the guise of illness in order to avoid the possibility of being tested. The ability to detect that specimens are or will be collected for random testing also provides an opportunity for individuals to be prepared to subvert the testing by procuring an adulterant or urine substitute

and keeping it available on their persons during the periods that specimens are collected. However, the NRC also recognizes that it is impossible to ensure that individuals are unable to detect the periods during which specimens are being collected. At a minimum, coworkers will be suspicious that collections are occurring if they observe an individual leaving the work site and returning within a short time, even if the supervisor and individual do not discuss the reason for the individual's short absence. Therefore, the proposed paragraph would require licensees and other entities to conduct random testing in a manner that would provide "reasonable assurance" that individuals are unable to predict when specimens will be collected, rather than requiring them to "ensure" that the period of time during which specimens will be collected cannot be detected. However, licensees and other entities would be required to minimize the likelihood that individuals who are subject to testing know that they are more likely to be called for testing at certain times than others.

Within this context, proposed §26.31(d)(2)(i)(A) would be added to require licensees and other entities to take reasonable steps to either conceal from the workforce that collections will be performed during a scheduled collection period, or create the appearance that specimens are being collected during a portion of each day on at least four days in each calendar week at each site. This proposed provision would require licensees and other entities to take reasonable steps to minimize the cues that persons may use to detect that specimens will be collected at a certain time. These cues may include, but are not limited to, the presence of a mobile collection facility on site and the presence of collectors at the site only on days that collections occur, or having the lights on in a designated collection site and occupying it only when the collection site is in use. A reasonable step to minimize cues associated with activities inside a collection site could be covering any outside windows so that a passerby cannot detect whether the collection site is occupied. Other steps to meet the proposed requirement could

include, but would not be limited to, stationing a mobile collection facility on site for some part of the day on four days each week or assigning individuals to staff the designated collection site during periods that specimens are not being collected during some portion of each day on at least four days in each calendar week. Maintaining the appearance that the collection site is active on more than half of the days in each week would make it more difficult for individuals to plan to subvert the testing process by leaving work when they believe specimens are being collected. The requirements in proposed §26.31(d)(2)(i) and (A) would be added to meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs, by reducing the opportunities for individuals to subvert the testing process by having advanced warning that specimens are being collected.

Proposed §26.31(d)(2)(i)(B) would amend the third sentence of current §26.24(a)(2), which requires that specimens must be collected "at various times during the day." The proposed rule would expand the current requirement to require licensees and other entities to "collect specimens on an unpredictable schedule, including weekends, backshifts, and holidays, and at various times during a shift." The purpose of the current and proposed provisions is to ensure that individuals cannot predict the times at which they will be tested, as well as prevent them from perceiving that there are "safe" periods during which they will not be tested that may lead them to believe they could engage in substance abuse without fear of detection. Varying the time periods during which specimens are collected on an unpredictable schedule would also increase the rule's effectiveness in deterring substance abuse. Adding this proposed provision would meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs.

Proposed §26.31(d)(2)(ii) would retain the third sentence of current §26.24(a)(2), which states that random testing must be administered on a nominal weekly frequency. The current

requirement to collect specimens for random testing at “various times during the day” would be retained in proposed §26.31(d)(2)(i)(B).

Proposed §26.31(d)(2)(iii) would require individuals who are selected for random testing to report to the collection site as soon as reasonably practicable after they have been notified that they have been selected for testing, within the time period established in the FFD policy. The necessity for the FFD policy to establish a time limit within which individuals must report for testing is discussed with respect to proposed §26.27(b)(2). Proposed §26.31(d)(2)(iii) would be added to further clarify this requirement by emphasizing the individual’s responsibility to report as soon as reasonably practicable after notification. For example, in order to cover all of the possible situations in which it may not be possible for an individual to immediately report for testing after notification (which could include the time required to travel to a collection site or to change clothes and be monitored for contamination after working under a radiation work permit), the FFD policy may permit individuals up to 2 hours to report for testing after notification. However, if there are no legitimate work, travel, or other demands that prevent an individual from immediately reporting for testing, the proposed provision would require the individual to report as soon as he or she is notified. This provision would strengthen FFD programs by further reducing opportunities for individuals to subvert the testing process, as discussed with respect to proposed §26.27(b)(2), and, therefore, would meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs.

Proposed §26.31(d)(2)(iv) would amend the first sentence of current §26.24(a)(2) to clarify that individuals who are off site and unavailable for testing when selected for a random test, must be tested at the earliest reasonable and practical opportunity. This proposed requirement would be added to prohibit licensees and other entities from returning these individuals’ names to the random testing pool without conducting a test, as has been some

licensees' practice. Returning the individuals' names to the random testing pool without conducting a test ensures that they are immediately eligible for another unannounced test, as required in proposed §26.31(d)(2)(v), but does not ensure that all individuals who are subject to this part have an equal probability of being tested. This proposed revision, therefore, would meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs.

The proposed paragraph would include the phrase, "at the earliest reasonable and practical opportunity when both the donor and collectors are available to collect specimens for testing," to clarify that licensees and other entities would not be required to call an individual back to the site if he or she is off site when selected for testing. In addition, the proposed provision would not require licensees and other entities to make special arrangements to ensure that a collector is available to collect the specimens as soon as the individual returns to the site. The NRC is aware that some licensees have called in individuals and collectors in the past under these circumstances. However, these practices may permit individuals to predict that they will be subject to testing when they return to the site, which would provide them with an opportunity to take actions to subvert the testing process, as discussed with respect to proposed §26.31(d)(2)(i). Therefore, the proposed paragraph would require licensees and other entities to collect specimens from an individual who is off site when selected for testing, in a manner that also ensures the individual does not have advance notification that he or she has been selected for testing. This proposed change would be made to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

Proposed §26.31(d)(2)(v) would retain the second sentence of §26.24(a)(2), which requires that an individual who has completed a test is immediately eligible for another random test.

Proposed §26.31(d)(2)(vi) would amend the last sentence of current §26.24(a)(2) in response to licensee implementation questions with respect to the meaning of the term, "workforce," in the current rule. These questions have related to whether "workforce" means all individuals who are employed by the licensee, including individuals who are not subject to Part 26, all individuals at a site, or all individuals who are subject to the licensee's FFD program. The proposed paragraph would clarify that the number of random tests that must be performed in a year must be equal to 50 percent of the population of individuals who are subject to random testing under the FFD program. If several sites are covered by a common FFD program, the "population" would include all individuals who are subject to the common FFD program. The population would also include individuals who have applied for authorization and who are subject to random testing under proposed §26.67 [Random drug and alcohol testing of individuals who have applied for authorization]. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.31(d)(3) [Drug testing] would be added to group requirements in one paragraph that are related to the general administration of drug testing. This proposed change would be made because requirements that address this topic are dispersed throughout the current rule whereas grouping them together in a paragraph would make them easier to locate within the proposed rule. The proposed reorganization would meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.31(d)(3)(i) would combine some of the requirements in current Section 1.1(3) in Appendix A to Part 26, §26.24(f), the first sentence of current Section 2.8(e)(1) in Appendix A, and current Section 4.1(a) and (b) in Appendix A to Part 26, which require licensees and other entities to use only HHS-certified laboratories to perform drug testing,

except if initial tests are performed at a licensee testing facility. Other detailed requirements in these sections would be retained, but presented in the appropriate sections in proposed Subparts E [Collecting specimens for testing], F [Licensee Testing Facilities], and G [Laboratories Certified by the Department of Health and Human Services]. The proposed rule would use the term, ”non-negative,” to replace the term, “presumptive positive,” in this paragraph and throughout the remainder of the rule to refer collectively to adverse validity and drug test results, as discussed with respect to the definition of “non-negative” in proposed §26.5 [Definitions]. These proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve the organizational clarity of the rule.

The proposed paragraph would also require that specimens sent to the HHS-certified laboratory by the licensee or other entity must be subject to initial validity and drug testing by the laboratory, and any specimens that yield non-negative initial validity or drug test results must be subject to confirmatory testing by the laboratory, except for invalid specimens that cannot be tested. Specimen validity testing refers to testing conducted by a laboratory to identify attempts to tamper with a specimen. Attempts to tamper with a specimen may include (1) adulteration, which means putting a substance into a specimen that is designed to mask or destroy the drug or drug metabolite that the specimen may contain or to adversely affect the assay reagent; (2) dilution, which means adding a liquid, which, by contrast to an adulterant, would not be detected by validity testing, to the urine specimen to decrease the concentration of a drug or metabolite below the cutoff concentration; and (3) substitution, which means replacing a valid urine specimen with a drug-free specimen. When HHS published its Notice of Proposed Revisions (66 FR 43876; August 21, 2001) to the HHS Guidelines to establish requirements for specimen validity testing performed by HHS-certified laboratories, the HHS reported that the number of adulterated and substituted urine specimens has been increasing among the

specimens tested under the Federal agency workplace drug testing program and the U.S. Department of Transportation (DOT) regulations (49 CFR part 40). Program experience gained since Part 26 was first promulgated has also indicated an increasing number of adulterated and substituted urine specimens submitted to HHS-certified laboratories from Part 26 testing programs. Although current Part 26 contains a number of requirements related to specimen validity (e.g., the fifth sentence of current Section 2.1(e), Section 2.4(f)(2), 2.4(g)(14)–(g)(16), and 2.7(d) in Appendix A to Part 26), the methods available to tamper with specimens have become more sophisticated since the rule was first published and more sophisticated methods of detecting tampering are necessary. Therefore, the proposed rule would incorporate new requirements for HHS-certified laboratories to conduct specimen validity tests that are consistent with similar provisions contained in the most recent revision to the HHS Guidelines (69FR 19643; April 13, 2004). These new requirements for specimen validity testing would be added to strengthen FFD programs by improving current laboratory procedures to detect specimens that are dilute, adulterated, or substituted, consistent with Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. Detecting specimen tampering is necessary to identify individuals who may attempt to hide drug abuse, because attempts to tamper with a specimen provide clear evidence that the individual is not trustworthy and reliable, and because these individuals' drug use may pose a risk to public health and safety and the common defense and security, as discussed with respect to proposed §26.23 [Performance objectives].

Proposed §26.31(d)(3)(ii) would amend the first sentence of current §26.24(d)(1), which permits licensees and other entities to conduct initial testing of urine specimens at a licensee testing facility, provided that the licensee testing facility 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. The proposed rule would add permission for licensees and other entities to perform initial validity testing at a licensee testing facility, for the reasons discussed with respect to proposed §26.31(d)(3)(i). Detailed requirements related to specimen validity testing at licensee testing facilities would be established in proposed Subpart F [Licensee Testing Facilities].

Proposed §26.31(d)(3)(iii) would be based upon the portions of current Sections 2.7(e)(1) and 2.7(f)(2) in Appendix A to Part 26 that establish the cutoff levels for initial and confirmatory drug testing, respectively, which licensees must apply under the current rule. However, the proposed paragraph would require FFD programs to apply the updated cutoff levels specified in proposed §26.163(a)(1) for initial drug testing and proposed §26.163(b)(1) for confirmatory drug testing. Consistent with the first sentence of current §26.24(b), the proposed paragraph would also permit FFD programs to implement more stringent cutoff levels than specified in the rule, but would establish additional requirements related to lower cutoff levels, as will be discussed further below. The permission in the first sentence of current §26.24(b) to implement a broader panel of drugs would be relocated to proposed §26.31(d)(1), as discussed with respect to that paragraph.

Proposed §26.31(d)(3)(iii)(A) would retain the third and fourth sentences of current §26.24(b) regarding management actions and sanctions for confirmed positive drug test results based on any lower cutoff levels established by the FFD program. The proposed rule would add a requirement that the lower cutoff levels must be documented in the FFD program's written policy and procedures to ensure that individuals who are subject to testing are aware of the cutoff levels that would be applied to their drug test results in order to protect their rights to due process. The proposed change would be made to meet Goal 7 of this rulemaking, which is to protect the due process rights of individuals who are subject to Part 26.

Proposed §26.31(d)(3)(iii)(B) would require that the FFD program's cutoff levels for drugs and drug metabolites, including any more stringent cutoff levels, must be uniformly applied in all tests conducted under this part and equally to all individuals who are subject to testing, except as permitted under proposed §26.163(a)(2) for dilute specimens and proposed §26.165(c)(2) for retesting specimens. As discussed with respect to proposed §26.31(d)(1)(ii), some FFD programs have adopted the practice of testing specimens at the assay's LOD for for-cause, post-event, and followup tests, which results in some individuals receiving unequal treatment under the rule. Therefore, the proposed paragraph would be added to meet Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Proposed §26.31(d)(3)(iii)(C) would be added to specify requirements for establishing more stringent cutoff levels. Before implementing the more stringent cutoff levels, licensees and other entities who are subject to the rule would be required to obtain certification from an independent forensic toxicologist that the more stringent cutoff levels are technically sound and legally defensible, with two exceptions. Certification by a forensic toxicologist would not be required if: (1) the U.S. Department of Health and Human Services lowers the cutoff levels in the HHS Guidelines for the same drugs or drug metabolites and the FFD program adopts the lower HHS cutoffs or (2) the licensee or other entity previously received written approval from the NRC to apply lower cutoff levels, in accordance with current Section 1.1(2) in Appendix A to Part 26. These proposed requirements would be consistent with those contained in proposed §26.31(d)(1)(i)(D) related to adding drugs to the panel of drugs for which testing is required under the rule and would be added here for the same reasons discussed with respect to that paragraph. Licensees and other entities would no longer be required to inform the NRC, in writing, that they have implemented new, lower cutoff levels because the purpose of the

reporting would be met by the forensic toxicologist's review. Therefore, these changes would be made to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements, while continuing to protect donors' right to accurate and reliable drug testing.

Proposed §26.31(d)(4) [Alcohol testing] would update current §26.24(g), which contains general requirements for conducting alcohol testing, to reflect other changes that would be made in the proposed rule. The current cross-reference to Section 2.7(o)(3) in Appendix A to Part 26 would be amended to refer to §26.91(a) in Subpart E [Collecting Specimens for Testing], which would contain detailed requirements for conducting alcohol testing. Reference to oral fluids as acceptable specimens for initial alcohol testing would be added to this paragraph. The basis for adding oral fluids as acceptable specimens for initial alcohol testing is discussed with respect to proposed §26.83 [Specimens to be collected]. The BAC at which a confirmatory test is required would be changed to 0.02 percent (from 0.04 percent) in the proposed paragraph for consistency with the revised alcohol cutoff levels in proposed §26.99 [Determining the need for a confirmatory test for alcohol] and proposed §26.103 [Determining a confirmed positive test result for alcohol]. The basis for the revised alcohol cutoff levels is discussed with respect to those sections. Reference to blood testing for alcohol would be deleted because donors would no longer be permitted to request blood testing for alcohol in the proposed rule, as discussed with respect to proposed §26.83(a).

Proposed §26.31(d)(5) [Medical conditions] would be added to address circumstances in which it may be impossible or inadvisable to test an individual using the procedures specified in this part. Circumstances have arisen under Part 26, as well as the programs of other Federal agencies, in which an individual's medical condition has made it inadvisable to implement testing procedures in accordance with the relevant requirements. Therefore, proposed

§26.31(d)(5)(i) would permit alternative specimen collection and evaluation procedures for rare instances in which it would be difficult or hazardous to the donor to collect breath, oral fluids, or urine specimens, including, but not limited to, required post-event testing when an individual has been seriously injured. Only the MRO would be permitted to authorize an alternative evaluation procedure, which may include, but is not limited to blood testing for alcohol. Proposed §26.31(d)(5)(ii) would be added to clarify that necessary medical treatment may not be delayed in order to conduct drug and alcohol testing. These proposed paragraphs would be consistent with the requirements of other Federal agencies and meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.31(d)(6) [Limitations of testing] would retain and amend current Section 2.1(d) in Appendix A to Part 26, which states that specimens collected under Part 26 may only be designated or approved for testing as described in this part and may not be used for any other analysis or test without the permission of the tested individual. The proposed paragraph would add examples of the types of analyses and tests that would be prohibited without the donor's written permission. Although the NRC is not aware of any instances in which such unauthorized testing has occurred in FFD programs under this part, the technology for performing these analyses and tests has become increasingly available since the regulation was first promulgated. These examples would be added to meet Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Section 26.33 Behavioral observation

Proposed §26.33 [Behavioral observation] would be added to emphasize that behavioral observation is a required element of FFD programs. The first sentence of proposed §26.33

would require behavioral observation of individuals who are subject to this part. The second sentence would retain current §26.22(a)(3), (a)(4), and (b), which state that the individuals who perform behavioral observation must be trained to do so, and extend the training requirement to all individuals who are subject to Part 26. The third sentence of the proposed paragraph would require that individuals must report FFD concerns arising from behavioral observation to the appropriate personnel designated in the FFD program procedures. These proposed changes would be made to strengthen the behavioral observation element of FFD programs by increasing the likelihood that impairment and other adverse behaviors are detected and appropriately addressed by the licensees and other entities who are subject to the rule.

Section 26.35 Employee assistance programs

Proposed §26.35 [Employee assistance programs] would amend current §26.25 [Employee assistance programs (EAP)] for the reasons discussed with respect to each paragraph that would be added to the proposed rule. Proposed §26.35(a) would retain the current provision.

In response to implementation questions, proposed §26.35(b) would be added to clarify that licensees and other entities are not required to provide EAP services to C/V employees who are working at a licensee's or other entity's facility and are subject to this part. This proposed provision would be consistent with the interpretation of the current rule in item 13.1.4 of NUREG-1354. However, the proposed rule would continue to require that C/V employees who are subject to Part 26 must have access to an EAP, and licensees and other entities who rely upon the C/V's FFD program would continue to be required to ensure that the C/V's EAP meets the requirements of this part. The proposed paragraph would be added to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

The proposed paragraph would also state that licensees and other entities need not provide EAP services to individuals who have applied for authorization to perform job duties that would require them to be subject to this part. Licensees and other entities would not be required to provide an EAP to applicants for authorization because these individuals would not yet be performing job duties that could affect public health and safety or the common defense and security. This proposed clarification would be added because applicants would be subject to other requirements under the proposed rule, as discussed with respect to proposed §26.25(d).

Proposed §26.35(c) would amend the last sentence of current §26.25 to emphasize that the identity and privacy of an individual who seeks EAP services must be protected and clarify the conditions under which an individual's confidentiality may or must be violated by EAP personnel. The proposed rule would permit EAP personnel to communicate information about an individual by name to the licensee or other entity under only two conditions: (1) if the individual waives the right to privacy, or (2) EAP personnel determine that the individual's condition or actions pose or have posed an immediate threat to himself or herself or others. The proposed provision would clarify the NRC's intent with respect to EAP confidentiality because the current provision has been misinterpreted.

The last sentence of current §26.25 requires confidentiality for individuals who seek EAP services, except if EAP professionals determine that the individual's condition "constitutes a hazard to himself or herself or others." Some licensees have over-interpreted this phrase and routinely require EAP staff to report individuals who self-refer for any reason, which is not the intent of this provision. The NRC is also aware that this phrase has been misinterpreted by some individuals who are subject to the rule as meaning that no self-referral to the EAP would remain confidential and that EAP staff always report self-referrals to licensee management.

This perception appears to be widely shared, including by individuals who are subject to FFD programs that have not misinterpreted the current rule and who correctly permit EAP staff to make the determination whether an individual's condition should be reported to licensee management.

A key purpose of requiring EAPs under Part 26 is to encourage individuals and their family members to self-refer for any type of problem that could potentially impair job performance, so that early intervention may be offered to prevent the problem from adversely affecting the individuals' job performance. Upon assessment, it is not uncommon for EAP staff to find that a developing substance abuse problem is contributing to a financial or family problem for which an individual has sought assistance. As a result, the EAP provides an important means to detect and achieve early resolution of developing substance abuse and other problems, which, if left untreated, could have the potential to adversely affect an individual's ability to safely and competently perform his or her job duties. The knowledge or perception among individuals who are subject to the rule that self-referrals to the EAP will be reported to management and will routinely result in the loss of authorization represents a significant barrier to the effectiveness of the EAP element of FFD programs. Therefore, the proposed paragraph would amend the last sentence of current §26.25 to clarify that an individual's use of the licensee's or other entity's EAP must remain confidential, except in very limited circumstances.

Proposed §26.35(c)(1) would be added to prohibit licensees and other entities from requiring the EAP to routinely report the names of individuals who self-refer to the EAP and the nature of the problems that led to the self-referral. The proposed provision would be necessary to: (1) eliminate some licensees' practices of requiring these reports, (2) protect individuals' privacy, and (3) strengthen the EAP element of FFD programs by eliminating a current barrier

to self-referrals in some FFD programs. The term, “routinely,” would be used to indicate that the proposed rule would permit EAP personnel to report individuals’ names and the nature of their problems if the individuals have waived the right to privacy in writing or EAP personnel determine that an individual’s condition or actions pose or have posed an immediate risk to public health and safety or the common defense and security. The proposed provision would not prohibit EAPs from reporting program utilization statistics or aggregated data that characterize the types of problems for which the program has provided services, because this type of information would not compromise individuals’ privacy.

Proposed §26.35(c)(2) would be added to provide further clarity in the language of the rule with respect to the conditions under which EAP personnel would be excepted from the confidentiality requirement in proposed §26.35(c) and required to report a concern about an individual to the licensee or other entity. The NRC is confident that EAP personnel have the qualifications and training necessary to continue to make the professional judgments required under the current and proposed rules in these circumstances. However, the proposed rule would include more detail with respect to the conditions and actions that an EAP professional would be required to report to ensure that licensees, other entities, and individuals who are subject to the rule better understand the intent of the current and proposed provisions. The proposed rule would require EAP personnel to report a concern about a specific individual to licensee or other entity management only when they have substantive reasons to believe that an individual’s condition or actions pose or have posed an immediate hazard to himself or herself or others. The phrase, “substantive reasons to believe,” would be used to clarify that casual and/or contextually appropriate comments made by an individual during a counseling session would not be a sufficient basis for reporting to the licensee or other entity. For example, an individual’s statement that he or she is concerned about becoming an alcoholic

would not constitute a substantive reason to believe that the individual's condition poses an immediate hazard. By contrast, this stated concern, in addition to evidence that the individual's personal relationships, financial condition, and/or health are suffering from his or her alcohol consumption, and any indications that the individual has been impaired while in a work status, would together constitute substantive reasons to believe that the individual's condition poses an immediate hazard and must be reported.

Proposed §26.35(c)(2)(i)–(c)(2)(iii) would be added to provide several examples of conditions and actions that would require EAP personnel to provide a report about an individual who has self-referred to licensee or other entity management. Proposed §26.35(c)(2)(i) would require reporting if the EAP staff has substantive reasons to believe that an individual may harm himself or herself or others, including, but not limited to, plans threatening suicide, radiological sabotage, or physical violence against others. Proposed §26.35(c)(2)(ii) would require reporting if the EAP staff has substantive reasons to believe that an individual has been impaired from drugs or alcohol while in a work status and is likely to be impaired in the future, as discussed with respect to proposed §26.35(c)(2). Proposed §26.35(c)(2)(iii) would require reporting if the EAP staff has substantive reasons to believe that an individual has committed any of the acts that would require a report to the NRC under proposed §26.219(b)(1)–(b)(3), including, but not limited to, the use, sale, distribution, possession, or presence of illegal drugs, or the consumption or presence of alcohol within a protected area or while performing job duties that require the individual to be subject to this part. The examples included in these proposed paragraphs are illustrative, but do not represent an exhaustive list of the conditions and actions that EAP staff may encounter that would be reported to licensee or other entity management under the proposed rule.

For additional clarity, proposed §26.35(c)(3) would be added to cross-reference the provisions in the proposed rule that would specify the actions that licensees and other entities would take after receiving a report from EAP personnel that an individual's condition or actions pose or have posed an immediate hazard to himself or herself or others. As discussed with respect to those paragraphs, proposed §§26.69(d) and 26.77(b) would require the licensee or other entity to take immediate action to: (1) prevent the individual from performing any job duties that require the individual to be subject to this part; (2) ensure that a determination of fitness is performed by a professional who has specific qualifications and training to address the nature of the individual's problem; and (3) either terminate the individual's authorization or ensure that the condition is resolved before permitting him or her to return to performing duties under this part.

These proposed changes to current §26.25 would be consistent with Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26, as well as Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

Section 26.37 Protection of information

Proposed §26.37 [Protection of information] would amend current §26.29, which contains requirements for protecting the personal information that must be collected under Part 26. In general, the proposed section would group requirements related to the protection of personal information that are dispersed throughout the current rule to aid in locating these requirements in the proposed rule. The records retention requirement in current §26.29(a) would be moved to proposed Subpart J [Recordkeeping and Reporting Requirements]. These

proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization of the rule.

Proposed §26.37(a) would combine and retain the first sentence of current §26.29(a) and the second sentence of current Section 3.1 in Appendix A to Part 26. The proposed paragraph would require licensees and other entities to establish and maintain a system of files and procedures to protect the personal information that is collected under this part and maintain and use such records with the highest regard for individual privacy.

Proposed §26.37(b) would amend current §26.29(b) and would divide it into several paragraphs for clarity. The first sentence of the proposed paragraph would amend the first sentence of current §26.29(b), which prohibits licensees and other entities from disclosing personal information collected under this part to any individuals other than those listed in the sentence. The proposed paragraph would continue to permit disclosure of the personal information to the listed individuals and would add permission for the licensee or entity to disclose the personal information to others if the licensee or other entity has obtained a signed release for such a disclosure from the subject individual. The proposed permission to release the personal information to individuals who are not listed in the paragraph with the written consent of the subject individual would be added because some licensees have misinterpreted the current requirement as prohibiting them from releasing the personal information under any circumstances, except to the parties listed in this paragraph. In some instances, such failures to release information have inappropriately inhibited an individual's ability to obtain information that was necessary for a review or appeal of the licensee's determination that the individual had violated the FFD policy. Therefore, the explicit permission for licensees and other entities to release personal information when an individual consents to the release, in writing, would be

added to meet Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Proposed §26.37(b)(1)–(b)(8) would list in separate paragraphs the individuals to whom licensees and other entities would be permitted to release personal information about an individual. Proposed §26.37(b)(3), (b)(4), and (b)(8) would retain unchanged the current permission for the release of information to NRC representatives, appropriate law enforcement officials under court order, and other persons as required by court order. Proposed §26.37(b)(1), (b)(2), (b)(5), and (b)(6) would amend the related requirements contained in current §26.29(b) to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule. The specific changes to current §26.29(b) would include the following:

Proposed §26.37(b)(1) would retain the current permission for the release of information to the subject individual and his or her designated representative. The proposed paragraph would add requirements for the individual to designate his or her representative in writing and specify the FFD matters to be disclosed. The proposed changes would be made in response to implementation questions from licensees. Licensees have sought guidance from the NRC related to the manner in which an individual must “designate” a representative.

Proposed §26.37(b)(2) would retain the current permission for the release of information to the licensee’s or other entity’s MROs. The proposed rule would also permit the release of information to MRO staff members for consistency with proposed §26.183(d), which would permit MRO staff to serve some MRO functions under the direction of the MRO. MRO staff would require access to the personal information in order to perform their job duties. The role of MRO staff in FFD programs is further discussed with respect to proposed §26.183(d).

Proposed §26.37(b)(5) would amend the current reference to licensee representatives who have a need to have access to the information in performing assigned duties. The current rule refers only to individuals who are performing audits of FFD programs. As a result, the current rule has been misinterpreted by some licensees as limiting the release of personal information only to such individuals. This was not the intent of the provision. Rather, the intent of the current rule was that licensees and other entities would be permitted to release information to their representatives who must have access to the personal information in order to perform assigned job duties. Therefore, the proposed rule would clarify that licensee representatives who perform determinations of fitness, such as the SAE (see the discussion of proposed §26.187) and human resources functions, as well as auditors and other representatives of the licensee or other entity, may be permitted access to personal information but only to the extent that such access is required to perform their assigned functions.

Proposed §26.37(b)(6) and (b)(7) would amend the portion of current §26.29(b) that refers to "persons deciding matters on review or appeal." The proposed changes would be made in response to implementation questions from licensees, including whether the rule covers persons deciding matters in judicial proceedings or only the internal appeals process specified in current §26.28 [Appeals] as well as whether information could be released in a judicial proceeding that was not initiated by the subject individual. The proposed rule would clarify that the permission includes individuals who are presiding in a judicial or administrative proceeding, but only if the proceeding is initiated by the subject individual in proposed §26.37(b)(6). Proposed §26.37(b)(7) would be added to cover "persons deciding matters under review in §26.39" [Review process for fitness-for-duty policy violations], as discussed with respect to that section.

Proposed §26.37(c) would be added to require the disclosure of relevant information to licensees and other entities, including C/Vs, and their authorized representatives who have a legitimate need for the information and a signed release from an individual who is seeking authorization under this part. This proposed provision would be added to further clarify current §26.29(b), because some licensees have misinterpreted the current provision as prohibiting the release of information to C/Vs who have licensee-approved FFD programs and conduct suitable inquiries on behalf of licensees and other entities. The proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.37(d)–(f) would retain several requirements related to the protection of information in the current rule but move them into this proposed section for organizational clarity. Proposed §26.37(d) would combine requirements in current §26.29(b) and Section 3.2 in Appendix A to Part 26, as they relate to an individual's access to records that are necessary for a review of an FFD policy violation. The proposed paragraph would retain the current requirements for licensees, other entities, HHS-certified laboratories, and MROs to provide the information that an individual requests related to a determination that the individual has violated the FFD policy on the basis of drug test results. Proposed §26.37(e) and (f) would retain current Section 3.1 in Appendix A to Part 26 and the last sentence of current §26.29(b), respectively.

Section 26.39 Review process for fitness-for-duty policy violations

Proposed §26.39 [Review process for fitness-for-duty policy violations] would amend current §26.28 [Appeals] and separate it into several paragraphs. The current section title would be revised to eliminate the implication that the internal management review is a legal

proceeding. Several requirements would be added to clarify and strengthen individuals' due process rights during the review, as follows:

Current §26.28 requires that individuals who are subject to the rule have an opportunity for a management review of a determination that the individual has violated the licensee's or other entity's FFD policy. Proposed §26.39(a) would retain the requirement that the review must be impartial and add a requirement that the review must be objective. The requirement for an objective review would be added because some licensees have permitted the same individuals who were involved in the initial determination that an individual violated the FFD policy to provide the review that is required under current §26.28. The impartiality of individuals who are reviewing their own decisions is questionable, and calls into question the effectiveness of the review process. Therefore, the proposed requirement for the review to be both impartial and objective would emphasize the NRC's intent that the review process must be effective.

In keeping with revisions to several other sections that would be intended to counter subversion of the testing process, proposed §26.39(a) would extend this opportunity to request a review to all FFD violations, including, but not limited to, violations based upon non-negative validity test results. The proposed paragraph would also clarify that applicants for authorization must be given the opportunity for a review. Experience with implementing this section of Part 26 has indicated that some licensees did not provide a review process to individuals who tested positive on pre-access tests. However, the factors that could produce false non-negative test results among licensee and C/V employees (e.g., administrative or testing errors) are equally likely to occur during pre-access testing of applicants for authorization. If applicants are not provided with a review process, it is possible that some of them would be effectively barred from the industry based on test results erroneously determined to be a violation of the

licensee's or other entity's FFD policy. Providing applicants with the opportunity to request a review would also enhance program credibility.

Proposed §26.39(b) would specify that FFD procedures must describe the contents and purpose of the notice that licensees and other entities would be required to provide to an individual who has violated an FFD policy and state that the individual may submit additional relevant information as part of the review process. This proposed clarification is necessary because experience with implementing current §26.28 has indicated that, in some cases, individuals do not understand the purpose of the review process and their associated rights.

Proposed §26.39(c) would require that more than one representative of the licensee's or other entity's management must conduct the review and that the reviewers may not be anyone who was involved in the original determination that the individual violated the FFD policy. These proposed clarifications are necessary because experience with implementing current §26.28 has indicated that, in some instances, the persons who were responsible for the initial determinations have been conducting reviews. The proposed requirements that the reviewers may not have been involved in the initial determination and that more than one management representative must conduct the review would strengthen the impartiality and objectivity of the review process in order to further enhance individuals' due process rights.

Proposed §26.39(d) would add a requirement that any records associated with the FFD policy violation must be deleted or corrected, as appropriate, if the policy violation decision is overturned. This requirement would be necessary because the proposed rule permits licensees and other entities to share and rely on information gathered by other Part 26 programs to a greater extent than currently. Therefore, incorrect records related to an FFD policy violation could effectively bar an individual from further employment under a Part 26 program if such information is transmitted to other licensees and entities who are considering whether to grant

authorization to an individual. The proposed requirement to delete or correct any records associated with an FFD policy violation that has been overturned would protect individuals from such potential adverse consequences.

Proposed §26.39(e) would amend the last sentence of current §26.28, which states that licensees and other entities are not required to provide a review procedure to a C/V's employees and applicants when the C/V is administering its own drug and alcohol testing. The proposed rule would amend the current paragraph in response to implementation questions from licensees who have asked whether the current provision excuses them from providing a review process for C/V employees at any time, including situations in which the FFD policy violation was determined as a result of testing conducted by the licensee. The proposed rule would revise this sentence to clarify that the licensee or other entity need not provide a review process if the FFD violation to be reviewed was identified through the C/V's drug and alcohol testing program. If the FFD violation was determined through the licensee's drug and alcohol testing, the licensee would continue to be required to provide the impartial and objective review.

Section 26.41 Audits and corrective action

Proposed §26.41 [Audits and corrective action] would rename and amend current §26.80 [Audits]. The phrase, "and corrective action," would be added to the section title to emphasize the NRC's intent that licensees and other entities must ensure that corrective actions are taken in response to any adverse findings resulting from an audit. In addition, the proposed rule would reorganize audit requirements in current §26.80, and move several audit and inspection requirements that are currently addressed in Appendix A to Part 26 into this section. These proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.41(a) [General] would amend the last sentence in current §26.80(a), which states that licensees retain responsibility for the effectiveness of C/V programs and the implementation of appropriate corrective action. The proposed paragraph would revise this requirement to include HHS-certified laboratories as well as any C/V FFD program elements and FFD programs upon which the licensee or other entity relies, which is consistent with the original intent of the current requirement. The proposed change would be to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

Proposed §26.41(b) [FFD program] would amend the required audit frequency in current §26.80(a). (The other requirements contained in current §26.80(a) are addressed in other paragraphs of proposed §26.41, as discussed with respect to the paragraphs of the proposed rule that address those topics.) The proposed rule would decrease the current 12-month FFD program audit frequency to a nominal 24-month frequency, which would grant a petition for rulemaking (PRM-26-1) submitted by Virginia Power on December 30, 1993. Experience with implementing Part 26 has shown that annual audits of the entire FFD program are unnecessary to ensure continued program effectiveness and, therefore, place an unnecessary burden on those entities who are subject to the rule. The proposed audit frequency would be decreased to 24 months to relieve this burden and to be consistent with the NRC's schedule for inspecting FFD programs. The proposed change would be consistent with Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Although the proposed rule would decrease the required audit frequency, licensees and other entities would be required to monitor program performance indicators and operating experience, consistent with a performance-based approach, and audit FFD program elements more frequently than every 24 months, as needed. In determining the need for more frequent audits, the proposed rule would require licensees and other entities to consider the frequency,

nature, and severity of discovered problems, testing errors, personnel or procedural changes, previous audit findings, and "lessons learned." The proposed change is intended to promote performance-based rather than compliance-based audit activities and clarify that programs must be audited following a significant change in personnel, procedures, or equipment as soon as reasonably practicable. The NRC recognizes that FFD programs evolve and new issues and problems continue to arise. Turnover of FFD program personnel and contracted services personnel, such as specimen collectors, exacerbates this concern. Licensee audits have identified problems that were associated in some way with personnel changes, such as new personnel not understanding their duties or procedures, the implications of actions that they took, did not take, or changes in processes. The purpose of these focused audits would be to ensure that changes in personnel, procedures, or equipment do not adversely affect the operation of the particular program element or function in question. Accordingly, the proposed audit requirement would ensure that any programmatic problems that may result from significant changes in personnel, procedures, or equipment are detected and corrected on a timely basis. This proposed change would be made to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs, by requiring more frequent audits of FFD program elements that may require closer monitoring than a nominal 24-month frequency would provide.

Proposed §26.41(c) [C/Vs and HHS-certified laboratories] would amend the audit and inspection requirements for these entities that are contained in the second sentence of current §26.80(a) and the third sentence of Section 2.7(m) in Appendix A to Part 26, as follows:

Proposed §26.41(c)(1) would further amend the requirement in current §26.80(a) for annual audits of C/V FFD programs and program elements and HHS-certified laboratories. The current annual audit frequency would be retained only for those portions of C/V FFD programs

whose personnel work off site and are not under the daily supervision of FFD program personnel. The activities of C/V personnel who work on site and are under the daily supervision of FFD program personnel would be audited under proposed §26.41(b). Retention of the annual audit requirement for C/Vs whose personnel work off site is necessary to ensure that the services provided continue to be effective, given that other means of monitoring their effectiveness, such as daily oversight, are unavailable. The proposed paragraph would also retain the annual audit requirement for HHS-certified laboratories. This audit frequency would be retained because of the key role the laboratories play in the overall effectiveness of Part 26 programs. Retention of these annual audit requirements in the proposed paragraph would deny the petition for rulemaking (PRM-26-1) submitted by Virginia Power on December 30, 1993.

Proposed §26.41(c)(2) would be added to relax some requirements related to annual audits and inspections of the HHS-certified laboratories upon which licensees and other entities rely for drug testing services. The proposed rule would permit licensees and other entities who are subject to the rule to rely upon the inspections of HHS laboratories that are performed for HHS-certification reviews and would no longer require licensees and other entities to audit the effectiveness of services that are reviewed by HHS inspectors. The current rule contains a number of requirements that are inconsistent with the requirements for drug testing of other Federally mandated programs. For example, the current rule permits donors to request confirmatory alcohol testing of a blood specimen at an HHS-certified laboratory, which is not permitted by other Federal agencies, and some of the cutoff levels established in the current rule are higher, in the case of testing for marijuana metabolite, or lower, in the case of testing for opiates, than other Federal agencies'. These programmatic discrepancies have made licensee audits of HHS-certified laboratories necessary to ensure the effectiveness of the unique drug and alcohol testing services required for Part 26 programs because these services

are not addressed in the HHS inspections. However, as discussed in Section IV. B, the proposed rule would eliminate the majority of such discrepancies. Therefore, the annual audits of HHS-certified laboratories by licensees that have been necessary under the current rule would be redundant under the proposed rule, except in certain conditions described below. The proposed change would be made to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Proposed §26.41(c)(2) would continue to require licensees and other entities to conduct annual audits of any services provided to the licensee or other entity that were not addressed in the annual HHS-certification review. This annual audit requirement would be retained because proposed §26.31(d) would retain the permission in the current rule for licensees and other entities to establish lower cutoff levels and test for drugs in addition to those for which testing is required under this part. If a licensee or other entity chooses to implement more stringent cutoff levels or a broader panel of drugs than required in the proposed rule, the licensee or other entity would be required to ensure that annual audits of the HHS-certified services related to those cutoff levels and drug tests are performed.

The last sentence of proposed §26.41(c)(2) would be added in response to stakeholder comments that were made during the public meetings discussed in Section V, related to the scope of the current audit requirements. The stakeholders noted that the scope of the current audit requirements is ill-defined in the current rule, which they believe has resulted in unnecessary variability between FFD programs and also an unnecessary burden. For example, the stakeholders noted that some FFD programs have interpreted the current rule as requiring annual audits of any substance abuse treatment program from which individuals who are subject to their FFD program may seek services as well as the entire national EAP company with whom the licensee or other entity contracts to obtain the services of one individual in the

local geographical area. The stakeholders suggested that such audits are costly and have little relationship to continuing FFD program effectiveness. The scope of audit requirements was not specified in the current rule because there is a wide variety of contractual relationships between licensees, other entities, and C/Vs for FFD program services that make it impractical to establish limits that would be universally applicable. However, the examples provided by the stakeholders at the public meeting were convincing that some limitations on the scope of the audit requirements would be appropriate in the proposed rule. Therefore, the proposed rule would not require licensees and other entities to audit organizations that do not routinely provide FFD services to the licensee or other entity, such as local hospitals or a substance abuse treatment facility. It would be unnecessary to audit these organizations because the FFD program would use their services infrequently, there would be a reasonable expectation of quality, and weaknesses in these services could be identified through other means. For example, under proposed §26.187 [Substance abuse professional], the SAE would be required to monitor the substance abuse treatment of individuals who require it and so would have the qualifications and information necessary to assess the quality of the treatment services an individual receives. The SAE would have the authority to seek other services on behalf of the FFD program if he or she identifies weaknesses in a treatment program. Therefore, this change would be made to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Proposed §26.41(d) [Contracts] would incorporate and amend the requirements of current Section 2.7(m) in Appendix A to Part 26 and others, which address contractual relationships to permit licensees and other entities access to the HHS-certified laboratories for the purposes of conducting the audits and inspections required under the rule. The portions of current Section 2.7(m) in Appendix A to Part 26 that relate to NRC inspections of HHS-certified

laboratories would be moved to §26.221 [Inspections] in Subpart K of the proposed rule, consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.41(d)(1) would amend the second sentence of current Section 2.7(m) in Appendix A to Part 26, which requires licensee contracts with HHS-certified laboratories for drug testing and alcohol confirmatory testing, as well as contracts for collection site services, to permit the licensee to conduct unannounced inspections. The proposed rule would retain the current requirement with respect to HHS-certified laboratories, and expand it to require that contracts with any C/V (which would include collection services providers) must permit the licensee or other entity to conduct audits at any time, including unannounced times, and to review all information and documentation that is reasonably relevant to the audits. The proposed paragraph would extend the current requirement to any C/V with whom the licensee or other entity contracts for FFD program services to enhance the effectiveness of the licensees' and other entities' audits should unannounced audits appear to be necessary. For example, a licensee or other entity may receive allegations that an off-site C/V is falsifying records or that a contract MRO or SAE is using drugs, and the licensee or other entity may determine that an unannounced audit would provide the most effective means to investigate such allegations. The proposed paragraph would ensure that the licensee's or other entity's contract with the C/V would permit the unannounced audit as well as access to any information necessary to conduct the audit. Therefore, this proposed change would be made to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

Proposed §26.41(d)(2) would be added to ensure that licensees' and other entities' contracts with C/Vs and HHS-certified laboratories permit the licensee or other entity to obtain

copies of and take away any documents that auditors may need to assure that the C/V, its subcontractors, or the HHS-certified laboratory are performing their functions properly and that staff and procedures meet applicable requirements. This proposed provision would respond to several incidents in which parties under contract to licensees did not permit Part 26 auditors to remove documents from a C/V's premises that were necessary to document audit findings, develop corrective actions, and ensure that the corrective actions were effective. Therefore, the proposed requirement would meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

The proposed paragraph would permit HHS-certified laboratories to reasonably limit the use and dissemination of the documentation that auditors copy and take away from the laboratories, in order to protect proprietary information and donors' confidentiality. This proposed permission would be added in response to stakeholder requests at the public meetings discussed in Section V. Because the current and proposed rules permit sharing of audit reports among licensees and C/Vs who rely on a laboratory, and it may be otherwise difficult to maintain appropriate control of proprietary information or donors' personal information, the NRC concurred with the stakeholders' request. This proposed change would meet Goal 7 of this rulemaking, as it relates to the privacy of individuals who are subject to Part 26, and would protect the trade secrets of HHS-certified laboratories who would continue to be subject to auditing under the proposed rule.

Proposed §26.41(d)(3) would amend the third sentence of current Section 2.7(m) in Appendix A to Part 26, which requires licensees and other entities to carry out inspections and evaluation of the procedural aspects of an HHS-certified laboratory's drug testing operations before awarding a contract to the laboratory, by adding a cross-reference to proposed §26.41(g). Proposed §26.41(g) would permit licensees and other entities to forego the

otherwise required pre-award evaluation under certain specific circumstances, as discussed with respect to that paragraph.

Proposed §26.41(e) [Conduct of audits] would retain the requirements in current §26.80(b).

Proposed §26.41(f) [Audit results] would retain the portion of current §26.80(c) that requires licensees and other entities to document audit findings and recommendations, report them to senior management, and document corrective actions taken in response to any identified adverse conditions. The proposed paragraph would also add two requirements. The second sentence of proposed §26.41(f) would specify the required content of audit reports to include identification of any conditions that are adverse to the proper performance of the FFD program, the cause of the condition(s), and, when appropriate, recommended corrective actions. The third sentence of the proposed paragraph would require licensees and other entities to review the audit findings and take corrective actions, including re-auditing of the deficient areas where indicated, to preclude, within reason, repetition of the condition. The proposed rule would add these two sentences for consistency with Criterion XVI in Appendix B to 10 CFR Part 50 to indicate that FFD audit reports are to be included in licensees' and other entities' corrective action programs. Some licensees have handled FFD audit reports outside of their normal corrective action programs, which address other conditions adverse to quality. As a result, some corrective actions for FFD program weaknesses have not been timely or effective. Therefore, the proposed rule would add these requirements to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

The last sentence of current §26.80(c), which refers to the requirements for auditing HHS-certified laboratories in Appendix A to Part 26, would be deleted as redundant with

proposed §26.41(c). This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization of the rule.

Proposed §26.41(g) [Sharing of audits] would respond to licensees' implementation questions related to the third and fourth sentences in current §26.80(a), which permit licensees and other entities to accept audits of C/Vs that are conducted by other FFD programs. The proposed paragraph would clarify the current permission to accept and rely on others' audits in response to implementation questions that the NRC has received from licensees with respect to the sharing of audits, as documented in Section 17 of NUREG-1354, and items 11.4 and 11.5 of NUREG-1385.

Proposed §26.41(g) would amend the current provision to incorporate specific permission for licensees and other entities to jointly conduct audits as well as rely on one another's audits. Reference to HHS-certified laboratories would also be added to indicate the applicability of these permissions to licensees' and other entities' audits of HHS-certified laboratories. These proposed changes would be consistent with the guidance issued by the NRC in the documents referenced above and current licensee practices. Therefore, the proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.41(g)(1) and (g)(2) would be added to require licensees and other entities to identify any areas that were not covered by a shared or accepted audit and ensure that any unique services used by the licensee or other entity that were not covered by the shared audit are audited. For example, an FFD program may use lower cutoff levels for drug testing than the FFD program(s) that conducted a shared audit with the result that the shared audit did not address the HHS-certified laboratories' procedures for testing at the first FFD program's lower cutoff levels. In this case, the first FFD program would not be permitted to rely on the shared

audit with respect to the lower cutoff levels and would be required to ensure that the HHS-certified laboratories' procedures for testing at the lower cutoff levels are audited separately (or in conjunction with other FFD programs who use the same cutoff levels). These proposed provisions would be consistent with the guidance issued by the NRC in the documents referenced above and current licensee practices. Therefore, the proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.41(g)(3) would retain the portion of the third sentence of current §26.80(a) that states that licensees and other entities need not re-audit the same C/V for the same period of time, and extend this permission to audits of HHS-certified laboratories. Extending the current provision to cover audits of HHS-certified laboratories would be consistent with the guidance issued by the NRC in the documents referenced above and current licensee practices. Therefore, this proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.41(g)(4) would retain the fourth sentence of current §26.80(a), which requires licensees and other entities to retain copies of the shared audit reports.

Proposed §26.41(g)(5) would be added to permit licensees and other entities to immediately obtain drug testing services from another HHS-certified laboratory, subject to certain conditions, in the event that the laboratory used by the licensee or other entity should lose its certification. Within 3 months of obtaining services from the replacement laboratory, the proposed paragraph would require the licensee or other entity to ensure that an audit is conducted of any aspects of the laboratory's services that are used by the licensee or other entity that have not been audited within the past 12 months by another licensee or entity who is subject to this part. This proposed provision would enhance the effectiveness of FFD programs

by ensuring that drug testing would not be interrupted or delayed if an HHS-certified laboratory loses its certification, as some licensees have experienced. The reliability of drug testing services provided by the replacement laboratory would be assured by the auditing and inspection activities of other licensees and entities who have been using the services of the replacement laboratory, as well as the audit conducted by the licensee or other entity of any services that have not been audited by other licensees or entities who are subject to this part. The proposed change would be made to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

Subpart C – Granting and Maintaining Authorization

Section 26.51 Purpose

A new §26.51 [Purpose] would be added to describe the purpose of the proposed subpart. Proposed §26.51 would emphasize that Subpart C contains “FFD requirements” for granting and maintaining authorization because the NRC has also published other requirements that establish additional steps that licensees and other entities must take as part of the process of determining whether to grant authorization to an individual. These additional requirements, found in particular in 10 CFR 73.56 and access authorization orders issued by the NRC to nuclear power plant licensees, require the licensee or other entity to conduct a psychological assessment and a credit and criminal history check of the individual, and to interview persons who have knowledge of the applicant for authorization. A central goal of adding Subpart C to the proposed rule is to eliminate redundancies and ensure consistency between the FFD requirements and these other requirements.

Section 26.53 General provisions

A new §26.53 [General provisions] would provide a generic summary of the requirements and process for determining whether individuals may be granted and maintain authorization.

Proposed §26.53(a) would introduce four new terms to Part 26: (1) “initial authorization,” (2) “authorization update,” (3) “authorization reinstatement,” and (4) “authorization with potentially disqualifying FFD information” These terms would be used to describe categories of proposed requirements for granting authorization. The proposed categories, which are based upon whether an individual who has applied for authorization has previously held authorization under Part 26 and the length of time that has elapsed since the individual’s last period of authorization ended, are defined in proposed §26.55 [Initial authorization], proposed §26.57 [Authorization update], proposed §26.59 [Authorization reinstatement], and proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information]. Proposed §26.53(a) would direct licensees or other entities to use the criteria for granting authorization to individuals found in proposed §§26.55, 26.57, 26.59, or 26.69, depending on which of the proposed sections would apply to the individual seeking authorization. The current rule in §26.27 discusses actions that the licensee must take before the initial granting of access or assignment of specified duties to an individual, but does not use the concepts of “initial authorization,” “authorization update,” “authorization reinstatement,” or “authorization with potentially disqualifying FFD information.” These concepts would be used in the proposed rule to focus the requirements for authorization more precisely on whether the individual has established a “track record” in the industry, and to specify the amount of original information gathering that licensees or other entities would be required to perform according to whether previous FFD programs have collected information about the individual. In addition, the same concepts are

used in access authorization requirements, so incorporating them into Part 26 would increase the consistency between the related regulations.

Proposed §26.53(b) would define the meaning of the term, “interruption,” which would be used in proposed §26.57 [Authorization update] and proposed §26.59 [Authorization reinstatement] to refer to the interval of time between periods during which an individual holds authorization under Part 26. Licensees and other entities would calculate an interruption in authorization as the total number of days falling between the day upon which the individual’s last period of authorization ended and the day upon which the licensee or other entity grants authorization to the individual. Proposed §26.53(b) would also specify that if potentially disqualifying FFD information is disclosed or discovered about an individual, licensees and other entities must implement the applicable requirements in proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information] in order to grant or maintain an individual’s authorization, rather than relying on the requirements in proposed §§26.55, 26.57, or 26.59, as discussed further with respect to proposed §26.69.

Proposed §26.53(c) would reiterate the FFD training requirements in proposed §26.29 [Training] and the fatigue training requirements in proposed §26.197(c) [Training and examinations] to clarify that all individuals must meet the applicable requirements for initial or refresher FFD training, as appropriate, before the licensee or other entity may grant authorization to the individuals. The proposed paragraph would repeat the training requirements for organizational clarity, because they apply to the authorization process. As discussed in Section V, stakeholders requested that the proposed rule present requirements in the order in which they would apply to licensees’ and other entities’ FFD processes. Therefore, the proposed paragraph would be added to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule

Proposed §26.53(d) would permit licensees and other entities to rely upon other licensees' or entities' Part 26 programs and program elements, as well as licensee-approved Part 26 programs and program elements of C/Vs, to meet the requirements of this subpart for granting and maintaining authorization. Proposed §26.53(d) would expand upon two sections of the current rule that similarly permit licensees and other entities to accept and rely upon other Part 26 programs and program elements. Specifically, current §26.24(a)(1) permits licensees to accept results from drug and alcohol tests that were administered under another Part 26 program within the past 60 days, and current §26.23 [Contractors and vendors] permits licensees to rely upon C/Vs' Part 26 programs that have been formally reviewed and approved by the licensee. Consistent with the principle of permitting licensees to accept and rely upon other Part 26 programs in their authorization decisions, guidance contained in NUREG-1385 also indicates that licensees may "accept" an authorization granted by a previous licensee for individuals who transfer between licensees with only a "short break" in authorization. The proposed rule would substantially increase the specificity of the requirements that must be met by licensees or other entities for granting authorization and establish detailed minimum standards that all programs must meet. These proposed detailed minimum standards are designed to address recent changes in industry practices that have resulted in a more transient workforce, as noted in the discussion of Subpart C in Section IV. B. Because the FFD programs of licensees and other entities would be substantially more consistent than in the past under these proposed detailed standards, permitting licensees and other entities to rely on other Part 26 programs to meet the proposed rule's requirements is reasonable and appropriate. In addition, the proposed provision would eliminate unnecessary redundancies in the steps required to grant authorization to an individual who is transferring from one Part 26 program to another.

Section 26.55 Initial Authorization

A new §26.55 [Initial authorization] would define the category of "initial authorization" requirements to apply both to individuals who have not previously held authorization under Part 26 and those whose authorization has been interrupted for a period of 3 years or more and whose last period of authorization ended favorably. Two considerations support the proposed requirement for individuals whose last period of authorization ended 3 or more years previously to satisfy the same requirements as individuals who have never previously held authorization. In general, the longer the period of time since the individual's last period of authorization ended, the greater the possibility that the individual has developed an active substance abuse problem or undergone significant changes in lifestyle or character that would diminish his or her trustworthiness, reliability, and ability to perform work safely and competently. Therefore, it is reasonable to require a full and extensive screening identical to that given an individual who has not held authorization, and has not been subject to drug and alcohol testing and behavioral observation, for 3 years or more. For similar reasons, access authorization requirements also require that individuals who have not held authorization for 3 years or more must be subject to the same screening as individuals who have not previously held authorization. Therefore, requiring individuals whose last period of authorization ended 3 or more years previously to satisfy the same requirements as individuals who have never held authorization would increase the consistency of Part 26 with the related access authorization requirements.

Proposed §26.55(a)(1) would require the licensee or other entity, before granting initial authorization to an individual, to obtain and review a self-disclosure in accordance with the applicable requirements of proposed §26.61 [Self-disclosure and employment history]. As discussed with respect to proposed §26.61, the self-disclosure and employment history would require the individual to report violations, if any, involving drugs or alcohol and the individual's

current and past employment history. The proposed requirement is similar to the requirement in §26.27(a)(1) of the current rule that a written statement must be obtained from the individual addressing the topics that are specified in current §26.27(a)(1). The discussion of proposed §26.61 compares the topics required to be addressed in the written statement under the current rule with the topics that would be addressed in the self-disclosure under the proposed rule. As discussed with respect to proposed §26.61(a)(3), the period of time to be addressed in the self-disclosure by an applicant for initial authorization would be the shorter period of either the past 5 years or the interval of time since the individual's eighteenth birthday.

Proposed §26.55(a)(2) would require the licensee or other entity, before granting initial authorization to an individual, to complete a suitable inquiry in accordance with the applicable requirements of proposed §26.63 [Suitable inquiry]. The proposed requirement is similar to the requirement in §26.27(a)(2) of the current rule that a suitable inquiry must be completed addressing the topics that are specified in §26.27(a)(2). The discussion of proposed §26.63 compares the topics that must be addressed in the suitable inquiry under the current rule with the topics that would be addressed in the suitable inquiry under the proposed rule. Proposed §26.63(f)(1) specifies that the period of time that the suitable inquiry would address for an initial authorization must be the shorter period of either the past 3 years or the interval of time since the individual's eighteenth birthday.

Proposed §26.55(a)(3) would require the licensee or other entity, before granting initial authorization to an individual, to ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of proposed §26.65 [Pre-access drug and alcohol testing]. Current §26.24(a)(1) requires testing within 60 days prior to the initial granting of unescorted access to protected areas or assignment to activities within the scope of Part 26. The discussion of proposed §26.65 compares the proposed pre-access drug and

alcohol testing requirements for initial authorization to the requirements in the current rule. Proposed §26.65 would require the licensee or other entity to ensure that the individual had negative drug and alcohol test results from testing that had been completed within the past 30 days before granting authorization to the individual, for the reasons discussed with respect to that section.

Proposed §26.55(a)(4) would require the licensee or other entity also to ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of proposed §26.67 [Random drug and alcohol testing of individuals who have applied for authorization]. Current §26.64(a)(2) requires unannounced drug and alcohol tests imposed in a statistically random and unpredictable manner. The discussion of proposed §26.67 compares the proposed random drug and alcohol testing requirements for initial authorization to the requirements in the current rule.

Proposed §26.55(b) would be added to require that the licensee or other entity must meet the requirements in proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information] to grant authorization to the individual, if potentially disqualifying FFD information is disclosed or discovered about the individual who is applying for authorization that has not previously been evaluated by another licensee or other entity.

Section 26.57 Authorization update

Proposed new §26.57 [Authorization update] would define the category of “authorization update” requirements for granting authorization to individuals whose authorization has been interrupted for more than 365 days but less than 3 years and whose last period of authorization was terminated favorably. As noted in the discussion of Subpart C in Section IV. C, the

proposed requirements for granting an authorization update would be less stringent than the proposed requirements for granting initial authorization. The proposed requirements would be less stringent for two reasons: (1) the individual who is applying for an authorization update would have a more recent "track record" of successful performance within the industry, and (2) the licensee or other entity would have access to information about the individual from the licensee or other entity who last granted authorization to him or her because of the increased information-sharing requirements of the proposed rule. However, the licensee or other entity would not have information about the individual's activities during the period of the interruption, so the proposed rule's requirements for an authorization update would focus on gathering and evaluating information from the interruption period. For example, in the case of an individual whose last period of authorization ended 2 years ago, the licensee or other entity would focus on gathering information about the individual's activities within the 2-year interruption period. If an individual's last period of authorization ended 13 months ago, the licensee or other entity would focus on gathering information about the individual's activities within those 13 months.

Proposed §26.57(a), like proposed §26.55(a), would require the licensee or other entity, before granting authorization, to: (1) obtain and review a self-disclosure in accordance with the applicable requirements of proposed §26.61; (2) complete a suitable inquiry in accordance with the applicable requirements of proposed §26.63; (3) ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of proposed §26.65; and (4) ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of proposed §26.67. However, proposed §26.61(c)(3)(iii) would limit the period of time to be addressed in the self-disclosure and employment history to the interruption period. That is, if an individual's last period of authorization ended 2 years ago, the self-disclosure and employment history would cover only

the past 2 years. Similarly, proposed §26.63(f)(2) would provide that the suitable inquiry for an authorization update must cover the interruption period. The proposed rule would require only that the interruption period must be addressed in the self-disclosure, employment history, and suitable inquiry because the licensee or other entity would obtain information from earlier periods in the individual's history from the licensee or other entity who had last granted authorization to the individual.

Proposed §26.57(b) would be added to specify that if potentially disqualifying FFD information is disclosed or discovered about the individual who is applying for authorization, the licensee or other entity may not grant authorization to the individual, except in accordance with proposed §26.69.

Section 26.59 Authorization reinstatement

A new §26.59 [Authorization reinstatement] would establish two categories of authorization reinstatement requirements for individuals whose authorization has been interrupted for a short period and whose last period of authorization was terminated favorably, for the reasons discussed in Section IV. C. One category of authorization reinstatement requirements would apply to individuals whose authorization has been interrupted for more than 30 days but no more than 365 days in proposed §26.59(a), and the other to individuals whose authorization has been interrupted for 30 or fewer days in proposed §26.59(c). The proposed steps for reinstating an individual's authorization after an interruption of 365 or fewer days would be less stringent than those required for initial authorization or an authorization update because these individuals have a recent, positive track record within the industry and so would pose little risk to public health and safety or the common defense and security.

The proposed requirements that are related to an individual whose authorization has been interrupted for more than 30 days but no more than 365 days would be more extensive than the requirements for granting authorization to an individual whose authorization has been interrupted for 30 or fewer days. The proposed requirements for the 31–365 day category would be consistent with those contained in the access authorization orders issued by the NRC to nuclear power plant licensees dated January 7, 2003. However, the proposed requirements for individuals whose authorization has been interrupted for 30 or fewer days would be more stringent than those contained in the access authorization orders issued by the NRC to nuclear power plant licensees dated January 7, 2003. Under the access authorization orders, licensees are required to obtain and review a self-disclosure and employment history from the applicant before reinstating the individual's authorization. Under the proposed rule, licensees and other entities would also be required to subject the individual to the possibility of being selected for pre-access testing in accordance with proposed §26.65(e) [Authorization reinstatement after an interruption of 30 days or less]. The NRC has determined that this additional proposed requirement is necessary to meet the proposed rule's performance objective of providing high assurance that individuals are trustworthy and reliable, as discussed with respect to proposed §26.23(a), by extending the deterrent effect of pre-access testing to individuals who have had an interruption in authorization of 30 or fewer days in length.

For individuals whose authorization has been interrupted for 31–365 days, proposed §26.59(a)(1) would require the licensee or other entity to obtain and review a self-disclosure and employment history in order to reinstate authorization. Consistent with the requirements for authorization updates in proposed §26.57, the proposed rule in §26.61(c)(3)(iii) would limit the period of time to be addressed in the self-disclosure and employment history to the period of the interruption in authorization. A self-disclosure and employment history for earlier periods of

time would be unnecessary because the granting licensee or other entity would have access to information about the individual from the licensee or other entity who had recently terminated the individual's authorization.

By contrast to the proposed requirements for an initial authorization and an authorization update, proposed §26.59(a)(2) would permit the licensee or other entity to reinstate an individual's authorization without first completing the suitable inquiry. The proposed rule would permit the licensee or other entity to reinstate the individual's authorization before completing the suitable inquiry because these individuals have a recent, positive track record within the industry and would pose little risk to public health and safety or the common defense and security. As would be required for an authorization update, the proposed rule would limit the period of time to be addressed by the suitable inquiry to the interruption period in proposed §26.63(f)(3). However, the proposed paragraph would require licensees and other entities to ensure that the suitable inquiry is completed within 5 days after reinstating the individual's authorization. If the suitable inquiry is not completed within the 5-day period permitted, the proposed rule would permit the licensee or other entity to maintain the individual's authorization for up to 10 days following the day upon which authorization was reinstated, but only if the licensee or other entity is unaware of any potentially disqualifying information about the individual. If the suitable inquiry is not completed within the 10 days permitted, the proposed rule would require the licensee or other entity to administratively withdraw the individual's authorization until the suitable inquiry is completed.

Proposed §26.59(a)(3) and (a)(4) would require the licensee or other entity to ensure that the individual whose authorization has been interrupted for 31–365 days is subject to pre-access drug and alcohol testing and random testing, respectively. Proposed §26.65(d) [Authorization reinstatement after an interruption of more than 30 days] would establish pre-

access drug and alcohol testing requirements for authorization reinstatements. Proposed §26.67 [Random drug and alcohol testing of individuals who have applied for authorization] would specify the requirements for random testing of individuals who are applying for an authorization reinstatement.

Proposed §26.59(b) would be added to ensure that any administrative withdrawal of authorization that would be required under proposed §26.59(a)(2) would not be reported or recorded as an unfavorable termination of authorization, unless and until the suitable inquiry is completed and it indicates that authorization should not be granted. This proposed provision would ensure that an individual's temporary administrative withdrawal of authorization, caused by a delay in completing the suitable inquiry, would not be treated as an unfavorable termination caused by an FFD violation. This proposed provision would be necessary to meet Goal 7 of this rulemaking, which is to protect the due process rights of individuals who are subject to Part 26, by ensuring that they are not subject to any adverse consequences for the licensee's or other entity's delay in completing the suitable inquiry.

Proposed §26.59(c) would establish authorization requirements for individuals whose authorization has been interrupted for 30 or fewer days. Proposed §26.59(c)(1) would require the licensee or other entity to obtain and review a self-disclosure from the applicant for authorization with certain exceptions that would be specified in proposed §26.61 [Self-disclosure and employment history]. The licensee or other entity would be permitted to forego conducting a suitable inquiry for individuals whose authorization has been interrupted for such a short period. Proposed §26.59(c)(2) would permit licensees and other entities also to forego pre-access drug and alcohol testing of individuals whose authorization has been interrupted for 5 or fewer days, but pre-access testing may be required under proposed §26.65(e) for individuals whose authorization has been interrupted for 6–30 days. Exceptions to the self-

disclosure and pre-access testing requirements in this proposed paragraph would be specified in proposed §§26.61 and 26.65, respectively.

26.61 Self-disclosure and employment history

A new §26.61 [Self-disclosure and employment history] would replace current §26.27(a)(1) for the reasons discussed in Section IV. C. The proposed rule would replace the term, "written statement," in the current rule with the phrase," self-disclosure and employment history," to more accurately characterize the requirement. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

Proposed §26.61(a) would be added to require licensees and other entities to obtain a written self-disclosure and employment history from every applicant before granting authorization to the individual, except in two circumstances, as follows:

Proposed §26.61(a)(1) would permit the licensee or other entity to forego obtaining a self-disclosure and employment history, if all three of the following conditions are met: (1) the individual previously held authorization under Part 26; (2) the individual's last period of authorization was terminated favorably; and (3) the individual was subject to a behavioral observation and arrest-reporting program that meets the requirements of this part throughout the time interval during which the individual's authorization was interrupted. The information to be obtained from the self-disclosure and employment history would be unnecessary in these circumstances, because it would already be available to the granting licensee or other entity from the Part 26 program that had been implementing the behavioral observation and arrest-reporting program during the interruption in the individual's authorization. A requirement for

licensees and other entities to conduct another suitable inquiry would be redundant and impose an unnecessary burden.

Proposed §26.61(a)(2) would permit licensees and other entities to forego obtaining an employment history from applicants for an authorization reinstatement whose authorization has been interrupted for 30 or fewer days. The employment history information would be unnecessary in this case, because the proposed rule would not require licensees or other entities to conduct a suitable inquiry for individuals who have had such a short break in authorization.

Proposed §26.61(b) would be added to specify the required content of the self-disclosure. Affirmative responses to any of the questions in proposed §26.61(b)(1) would be considered potentially disqualifying FFD information, as defined in proposed §26.5 [Definitions]. The proposed rule would expand the scope of the questions to be asked from those required in current §26.27(a)(1) in order to provide greater assurance that individuals would disclose information with regard to indicators of an active substance abuse problem or an increased risk of recidivism into an active substance abuse problem after treatment. Current §26.27(a)(2) requires information about whether the applicant "tested positive for drugs or use of alcohol that resulted in on-duty impairment." Proposed §26.61(b)(1) would require information about whether the applicant used, sold, or possessed illegal drugs, subverted or attempted to subvert a drug or alcohol testing program, or refused to take a drug or alcohol test. Both current §26.27(a)(2) and proposed §26.61(b)(1) require information on whether the applicant has been subject to a plan for substance abuse treatment (except for a self-referral). Both require information about previous denials or terminations of authorization.

Proposed §26.61(b)(2) would be added to require the applicant to disclose the circumstances surrounding any potentially disqualifying FFD information and the resolution of

the matter. For example, proposed §26.61(b)(1) would require an applicant to report an arrest on drug-related charges, while proposed §26.61(b)(2) would require the applicant to report the outcome of the arrest (e.g., charges, a conviction, a finding of not guilty, the dropping of the charges).

Proposed §26.61(b)(3) would define the time period to be addressed in the self-disclosure. The proposed rule would establish a time limit on the number of years in the past that an individual would be required to report and account for potentially disqualifying FFD information. One purpose of the self-disclosure is to identify indicators of an active substance abuse problem or an increased risk of recidivism into an active substance abuse problem after treatment. The relevant research literature indicates that there is a decrease in post-treatment recidivism (i.e., relapse) rates after 3 years of no further substance abuse, and a larger decrease in the recidivism rate after 5 years. If no indicators of a substance abuse problem within the past 5 years are disclosed (or since the applicant's eighteenth birthday in the case of an applicant who is less than 23 years of age), an applicant for initial authorization (see proposed §26.55) would not be required to disclose earlier substance-abuse-related events. For applicants who held authorization within the past 3 years, the self-disclosure would address only the time interval since the individual's last period of authorization ended. However, the licensee or other entity would obtain further information about the applicant over the past 5 years from reviewing the information made available by licensees or other entities who had granted authorization to the applicant in the past. This information would include information developed as part of previous suitable inquiries (see proposed §26.63) as well as information from the period(s) during which the individual was subject to other Part 26 programs.

Proposed §26.61(c) would be added to require applicants to provide information about current and past employers, which the licensee or other entity would then use for the suitable inquiry, if a suitable inquiry is required under proposed §26.63 [Suitable inquiry].

Proposed §26.61(d) would replace and expand upon current §26.27(a)(4). The proposed rule would add falsification of the self-disclosure or employment history as sufficient reasons to deny authorization to an individual in order to deter falsification attempts. Reference to temporary access authorization would be deleted from the proposed paragraph because temporary access authorization would no longer be permitted under Part 26, for the reasons discussed in Section IV. C.

Section 26.63 Suitable inquiry

A new §26.63 [Suitable inquiry] would amend current §26.27(a)(2) and the requirements related to conducting a suitable inquiry that are contained within the definition of the term, "suitable inquiry," in current §26.3 [Definitions]. The current rule defines a suitable inquiry as a "best-effort verification of employment history for the past 5 years, but in no case less than 3 years, obtained through contacts with previous employers to determine if a person was, in the past, tested positive for illegal drugs, subject to a plan for treating substance abuse, removed from, or made ineligible for activities within the scope of 10 CFR Part 26, or denied unescorted access at any other nuclear power plant or other employment in accordance with a fitness-for-duty policy." In general, the proposed changes to the current requirements are intended to: (1) better focus the suitable inquiry on indicators of an active substance problem and/or an increased risk of recidivism into an active substance abuse problem following treatment, as discussed in Section IV. C; (2) increase the consistency in implementing suitable inquiries among FFD programs by providing more detailed requirements, also as discussed in

Section IV. C; and (3) improve Part 26 by eliminating or modifying unnecessary requirements, which is Goal 5 of this rulemaking, as discussed in Section IV. B.

For all authorization categories, the suitable inquiry would be more thorough than previous industry practices, in order to increase the likelihood that potentially disqualifying FFD information would be identified, if it existed, and to provide high assurance that individuals are trustworthy and reliable, as demonstrated by avoiding substance abuse. For individuals who have established a recent, favorable work history under Part 26, as demonstrated by having held authorization that was terminated favorably within the past 3 years, the period of time addressed in the suitable inquiry would be reduced from the past 5 years in every case, to the past 3 years or less, depending upon how recently the applicant held authorization. If potentially disqualifying FFD information within the past 5 years is identified regarding an applicant and the information has not been addressed and favorably resolved by a previous licensee or other entity, the suitable inquiry requirements would be more extensive, as described in proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information].

Proposed §26.63(a) would be added to require licensees and other entities to conduct a suitable inquiry for two purposes. One purpose would be to verify the information provided by the applicant in the self-disclosure and employment history obtained under proposed §26.61. The second purpose would be to determine whether additional potentially disqualifying FFD information is available regarding the applicant. The proposed paragraph would also establish the circumstances in which a licensee or other entity would be permitted to forego the suitable inquiry in order to grant authorization to individuals. A licensee or other entity would be permitted to forego the suitable inquiry if all three of the following conditions are met: (1) the individual previously held authorization under Part 26; (2) the individual's last period of

authorization was terminated favorably; and (3) the individual was subject to a behavioral observation and arrest-reporting program that meets the requirements of this part throughout the period during which the individual's authorization was interrupted. The information to be obtained from a suitable inquiry would be unnecessary in these circumstances, because it would already be available to the granting licensee or other entity from the Part 26 program that implemented the behavioral observation and arrest-reporting program during the interruption in authorization.

Proposed §26.63(b) would be added to permit licensees and other entities to rely upon suitable inquiry information that was gathered by previous licensees and other entities who are subject to this part. This proposed provision would reduce the number of redundant suitable inquiries that licensees and other entities must conduct, when the suitable inquiries would address the same employers and same time periods. The proposed paragraph would also permit licensees and other entities to accept the results of any determinations of fitness that were performed under a previous Part 26 program, rather than requiring each new licensee and other entity to reevaluate the same information that was reviewed and resolved in accordance with the same requirements under another Part 26 program. This proposed change would be made to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Proposed §26.63(c) would be added to specify requirements for the manner in which licensees and other entities must conduct the suitable inquiry. Licensees and other entities would be required to demonstrate a "best effort" to complete the suitable inquiry. The "best effort" criterion recognizes licensees' and other entities' status as commercial entities with no legal authority to require the release of the information from other private employers and educational institutions. Because of privacy and potential litigation concerns, some private

employers and educational institutions may be unable or unwilling to release qualitative information about a former employee or student. For example, a former employer may verify the dates that an individual was employed by the company, but may be unwilling to reveal that the individual had been in treatment for drug or alcohol abuse while employed with the company. Therefore, the "best effort" criterion would require licensees and other entities to seek suitable inquiry information from the primary source (e.g., a company, private employer, or educational institution that the applicant has listed on his or her employment history), but recognizes that it may not be forthcoming. The "best effort" criterion in the proposed paragraph would be consistent with the "best-efforts basis" in current §26.27(a)(2), but the proposed rule would provide more detailed requirements in response to questions that the NRC has received from licensees about implementing a suitable inquiry on a "best effort" basis since Part 26 was first promulgated.

Proposed §26.63(c)(1) would be added to specify the type of information that the licensee or other entity must seek from employers regarding the applicant for authorization. The proposed paragraph would require the licensee or other entity to ascertain the reason that the individual's employment was terminated, his or her eligibility for rehire, and other information that could reflect on the individual's fitness to be granted authorization. The proposed requirement to obtain this information would be consistent with long-standing industry practices related to granting access authorization and related requirements in the access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Proposed §26.63(c)(2) would specify the type of information that licensees and other entities must seek when an applicant's claimed periods of employment include military service. The proposed requirement would be added for consistency with related requirements in the

access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Proposed §26.63(c)(3) also would be added to provide consistency with related requirements in the access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. The proposed paragraph would address circumstances in which a primary source of information refuses to provide the necessary suitable inquiry information or indicates an inability or unwillingness to provide it within 3 days of the request. Licensees and other entities would be required to document that the request for information was directed to the primary source and the nature of the response (i.e., a refusal, inability, or unwillingness). If a licensee or other entity encounters the circumstances addressed in proposed §26.63(c)(3), the proposed paragraph would require the licensee or other entity to seek suitable inquiry information from an alternate source, to the extent of the alternate source's ability to provide the information. An alternate source may include, but would not be limited to, a co-worker or supervisor at the same company who had personal knowledge of the applicant, if such an individual could be located. However, the proposed rule would prohibit the licensee or other entity from using the alternate source of suitable inquiry information to meet any other access authorization requirements for a character reference. The proposed rule would permit licensees and other entities to grant authorization, if warranted, when a response has been obtained from an alternate source, without waiting more than 3 days after the request for information was directed to a primary source. These proposed alternative methods of meeting the suitable inquiry requirement are necessary because, as discussed with respect to proposed §26.63(c), some employers are unwilling or unable to provide suitable inquiry information.

Proposed §26.63(d) would be added to require licensees and other entities who are subject to this part to share suitable inquiry information that they have collected when contacted by another licensee or entity who has a release that would permit the sharing of that information signed by the applicant for authorization. This proposed provision would restate the permission to release suitable inquiry information in current §26.29(b) as a requirement that licensees and other entities must share the information necessary to conduct the suitable inquiry. The proposed provision would also clarify that the information must also be released to C/Vs who have licensee-approved FFD programs when the C/V presents the required signed release from the applicant. This proposed clarification is necessary because some licensees have misinterpreted current §26.29(b) as prohibiting the release of suitable inquiry information to C/Vs who have licensee-approved FFD programs. The proposed paragraph would also permit a licensee or other entity to deny authorization to an individual if the individual will not sign the release necessary to permit the licensee or other entity to conduct the suitable inquiry. The proposed provisions would be consistent with access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Proposed §26.63(e) would be added to permit licensees and other entities to use electronic means of obtaining the suitable inquiry information. This proposed permission would be consistent with access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. The proposed paragraph would also add cross-references to the applicable records retention requirements in proposed §26.211 [General provisions] and proposed §26.213 [Recordkeeping requirements for licensees and other entities] in proposed Subpart J [Recordkeeping and Reporting Requirements] to ensure that licensees and other entities are aware of the

applicability of these requirements to the suitable inquiry information obtained electronically. The proposed change would be consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule

Proposed §26.63(f) would be added specify the period(s) of time that the suitable inquiry must address for applicants for initial authorization, authorization update, and authorization reinstatement. The proposed paragraph would also specify additional requirements for conducting the suitable inquiry for these authorization categories, as follows:

Proposed §26.63(f)(1) [Initial authorization] would require licensees and other entities to conduct a suitable inquiry to address the 3-year period preceding the date upon which the individual applies for authorization. The period of time to be addressed in the suitable inquiry for applicants for initial authorization who do not disclose any potentially disqualifying FFD information would be reduced from 5 years in the current regulation to 3 years for two reasons: First, one purpose of the suitable inquiry is to identify indicators of an active substance abuse problem or an increased risk of recidivism following treatment. Therefore, if no potentially disqualifying FFD information is disclosed by an applicant for initial authorization from the past 5 years and none is identified through the suitable inquiry or other means, it is unlikely that the applicant has an active substance abuse problem. Therefore, seeking a full 5 years of information about the individual would unlikely provide useful information and imposes an unnecessary burden. Second, industry experience has shown that employers are often reluctant to disclose adverse information to other private employers about former employees, and that the longer it has been since an individual was employed, the less likely it is that a former employer will disclose useful information. Therefore, rather than retaining the requirement for a 5-year suitable inquiry in all cases, the proposed rule would increase the thoroughness of the suitable inquiry into the past 3 years.

Proposed §26.63(f)(1) would be added to require the licensee or other entity to conduct the suitable inquiry with every employer by whom the applicant claims to have been employed within the past year. This proposed requirement to conduct the suitable inquiry with every claimed employer would be a more rigorous suitable inquiry than was common industry practice prior to issuance of the January 7, 2003, access authorization orders, which imposed additional compensatory measures related to access authorization. The purpose of contacting every employer would be to ensure that the licensee or other entity sought information related to any active substance abuse problem. For the earlier 2 years of the suitable inquiry period, the proposed paragraph would require the licensee or other entity to conduct the suitable inquiry with every employer by whom the applicant claims to have been employed the longest within each calendar month. Contacting these employers would increase the likelihood that the employers would have knowledge of the applicant and so may provide more useful information than contacting employers by whom the applicant was employed only briefly.

Proposed §26.63(f)(2) [Authorization update] would be added to specify the period of time that the suitable inquiry must address for applicants for an authorization update (i.e., those who held authorization within the past 3 years and whose last period of authorization was terminated favorably, but who have not held authorization within the past year). The proposed paragraph would require the licensee or other entity to conduct the suitable inquiry in the same manner as described in proposed §26.63(f)(1). However, for an authorization update, the suitable inquiry would address only the period that the individual's authorization was interrupted, rather than the full 3 years that would be required for initial authorization. A 3-year period for the suitable inquiry would be unnecessary for these individuals, because the licensee or other entity would have access to the information about the individual that was gathered by the

licensee or other entity under whose program the individual had been granted and successfully maintained authorization within the past 3 years.

Proposed §26.63(f)(3) [Authorization reinstatement after an interruption of more than 30 days] would specify the period of time that the suitable inquiry must address for applicants who held authorization within the past year and whose last period of authorization was terminated favorably, but who have not held authorization within the past 30 days. The proposed rule would require licensees and other entities to contact employers by whom the applicant claims to have been employed the longest in each calendar month of the interruption. The proposed rule would not require licensees and other entities to contact every employer by whom the individual claimed to have been employed during the interruption for the reasons discussed with respect to proposed §26.59(a)(2). Because these individuals have had only a short break in authorization, a sampling of employers from the interruption period would be sufficient to determine whether any indications exist that the individual had developed a previously undetected substance abuse or other problem that would adversely affect his or her fitness to have authorization reinstated.

The time periods and approach to conducting the suitable inquiry established in proposed §26.63(f)(1)–(f)(3) would be consistent with those established in the access authorization orders issued to nuclear power plant licensees dated January 7, 2003.

26.65 Pre-access drug and alcohol testing

Proposed §26.65 [Pre-access drug and alcohol testing] would amend current §26.24(a)(1), which requires drug and alcohol "testing within 60 days prior to the initial granting of unescorted access to protected areas or assignment to activities within the scope of this

part." The proposed section would amend the current pre-access drug and alcohol testing requirement for individuals who are seeking authorization under Part 26 to strengthen the effectiveness of FFD programs, as discussed in Section IV. C.

Proposed §26.65(a) [Purpose] would be added to describe the purpose of the section and identify the individuals to whom the requirements in the proposed section would apply. The pre-access testing requirements in this section would cover applicants for authorization (1) who have never held authorization under Part 26 or have held authorization under Part 26 and whose most recent period of authorization was terminated favorably, and (2) about whom no potentially disqualifying FFD information has been discovered or disclosed that was not reviewed and favorably resolved by another licensee or entity. Requirements for granting authorization to individuals whose previous periods of authorization were terminated unfavorably or denied, or about whom new potentially disqualifying FFD information has been discovered or disclosed, would be contained in proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information].

Proposed §26.65(b) [Accepting tests conducted within the past 30 days] would be added to permit licensees and other entities to forego pre-access testing of an individual who has negative test results from drug and alcohol tests that were performed in accordance with the requirements of Part 26 within the 30-day period before the licensee or other entity grants authorization to the individual, including tests that were conducted before the individual applied for authorization from the licensee or other entity. For example, if an individual was subject to random testing under another Part 26 program and was selected for testing under the other program before applying for authorization from the granting licensee or other entity: the proposed rule would permit the granting licensee or other entity to accept negative test results from the random test in lieu of performing a pre-access test, if the random test was conducted

within 30 days before the day upon which authorization is granted to the individual. A requirement for the licensee or other entity to conduct pre-access testing in these circumstances would be redundant and unnecessary.

Proposed 26.65(c) [Initial authorization and authorization update] would be added to establish pre-access testing requirements for individuals who are applying for initial authorization and an authorization update. The proposed rule would require negative results from pre-access testing before the licensee or other entity could grant authorization to the individual, except in the two circumstances described in proposed §26.65(c)(1) and (c)(2). In proposed §26.65(c)(1), licensees and other entities would be permitted to forego pre-access testing if the applicant had been subject to drug and alcohol testing (including random testing), behavioral observation, and arrest-reporting requirements under a Part 26 FFD program throughout the period during which the individual's authorization was interrupted. In proposed §26.65(c)(2), licensees and other entities would be permitted to forego pre-access testing of an applicant who had negative test results from Part 26 drug and alcohol tests that were performed within the past 30 days and was subject to behavioral observation and arrest-reporting requirements during the time interval between the day upon which the specimens were collected and the day the licensee or other entity grants authorization to the individual. Pre-access testing in these two circumstances would be unnecessary because there would be sufficient opportunity to detect substance abuse without it.

Proposed paragraphs §26.65(d) [Authorization reinstatement after an interruption of more than 30 days] and (e) [Authorization reinstatement after an interruption of 30 days or fewer] would be added to establish requirements for pre-access testing of individuals who are applying for an authorization reinstatement. The proposed requirements for pre-access testing of these individuals would be less stringent than the requirements for initial authorization and an

authorization update. The proposed provision would also relax the pre-access testing requirements in current §26.24(a)(1), which require all applicants for authorization to be subject to pre-access testing within 60 days before granting authorization. Less stringent pre-access testing requirements would be appropriate because these individuals have (1) met the rigorous criteria for initial authorization; (2) established a recent record of successfully maintaining authorization under Part 26; and (3) had only a short break in authorization.

Proposed §26.65(d) would specify pre-access testing requirements for individuals whose authorization has been interrupted for more than 31 days but no more than one year. Proposed §26.65(d)(1)(i) would require the licensee or other entity to administer an alcohol test and collect a urine specimen for drug testing. The licensee or other entity would be permitted to reinstate the individual's authorization if the alcohol test results are negative, before the drug test results are available. Proposed §26.65(d)(1)(ii) would permit the licensee or other entity to maintain the individual's authorization for 5 days after reinstatement without receiving the drug test results. But, if the licensee or other entity does not receive negative drug test results within 5 days of reinstating the individual's authorization, the proposed rule would require the licensee or other entity to administratively withdraw the individual's authorization until negative drug test results are received. These proposed requirements would ensure that individuals whose authorization has been interrupted for more than 30 days are subject to pre-access drug and alcohol testing to deter substance abuse and to detect any current substance abuse problem. However, the proposed provisions would not unduly delay authorization reinstatement, given that these individuals' recent successful histories of maintaining authorization under Part 26 indicates that they are at low risk of engaging in substance abuse. Proposed §26.65(d)(2) would permit licensees and other entities to forego pre-access testing of these applicants for reinstatement in the circumstances discussed with respect to proposed §26.65(c)(1) and (c)(2).

Proposed §26.65(e)(1) would be added to permit licensees and other entities to forego pre-access testing of applicants whose authorization has been interrupted for 5 or fewer days. This proposed provision would be consistent with current licensee practices and recommendations regarding “short breaks” in authorization in NUREG-1385 and other access authorization requirements.

However, proposed §26.65(e)(2) would require licensees and other entities to subject applicants whose authorization has been interrupted for 6–30 days to the possibility of being selected for pre-access testing in order to deter any potential for substance abuse. Proposed §26.65(e)(2)(i) would require the licensee or other entity to subject the applicant to a one-time chance of being selected for testing at a probability of approximately 4 percent. This proposed probability approximates the likelihood that individuals who are subject to random testing at the 50 percent annual testing rate in proposed §26.31(d)(2)(vi) would be selected for testing at some point within a 30-day period. Proposed §26.65(e)(2)(ii) would clarify that, if an applicant is not selected for pre-access testing under the preceding paragraph, the licensee or other entity would not be required to perform a pre-access test. Proposed §26.65(e)(2)(iii)(A) and (B) would specify requirements for conducting the pre-access testing, should an individual be selected for testing under proposed §26.65(e)(2)(i). The licensee or other entity would complete an alcohol test and collect a specimen for drug testing before reinstating the individual’s authorization. In order to maintain the individual’s reinstated authorization, the proposed rule would require that the licensee or other entity must receive negative drug test results within 5 days after reinstatement or administratively withdraw the individual’s authorization until negative drug test results are received. However, proposed §26.65(e)(3) would permit licensees and other entities to forego subjecting an individual to the possibility of being selected for pre-access testing, if the applicant had been subject to the drug and alcohol

testing (including random testing), behavioral observation, and arrest-reporting elements of a Part 26 FFD program throughout the interruption in the individual's authorization; because being subject to these program elements during the interruption period would be sufficient to deter substance abuse and provide assurance that substance abuse would be detected. Proposed §26.65 would enhance the deterrent effect of pre-access testing for individuals who have had a very short break in authorization, without imposing the burden of requiring that every individual must be tested.

Proposed §26.65(f) [Time period for testing] would be added to require that specimens that are collected for any pre-access testing required in this proposed section must be collected within the 30-day period preceding the day upon which the licensee grants authorization to an individual. Under current §26.24(a)(1), licensees and other entities are permitted to complete pre-access testing within the 60-day period before authorization is granted. The shorter time period within which pre-access testing must be conducted, if required, in the proposed rule would increase the likelihood of detecting an active substance abuse problem among applicants for unescorted access to nuclear power plants and others who are subject to Part 26 by increasing the number of pre-access tests that would be performed. In addition, the decreased time period for pre-access testing would increase the likelihood that recent drug use, particularly marijuana, would be detected before the concentration of metabolites in an individual's body could decrease below the cutoff levels prescribed in the proposed rule. The decreased time period within which pre-access testing must be performed in the proposed rule would provide higher assurance that individuals subject to this part are trustworthy and reliable, as demonstrated by the avoidance of substance abuse, as discussed with respect to proposed §26.23(a).

Proposed §26.65(g) [Administrative withdrawal of authorization] would be added to ensure that the licensee or other entity does not record or report as an unfavorable termination any administrative withdrawal of authorization that may be required under proposed paragraphs (d)(1)(ii) or (e)(2)(iii)(B) of this proposed section. The point in time at which a licensee or other entity receives drug test results would not be under the control of the applicant and would not reflect upon the applicant's fitness, trustworthiness, or reliability, if the licensee or other entity is unable to obtain drug test results within the 5 days permitted and must administratively withdraw the individual's authorization. Therefore, subjecting the individual to the severe consequences associated with a record of an unfavorable termination would be inappropriate. Should the drug test results be non-negative and the licensee or other entity terminates the individual's authorization for cause, however, the termination would then be recorded as unfavorable.

Proposed §26.65(h) [Sanctions for a confirmed non-negative pre-access test result] would be added to specify the minimum sanctions to be imposed on an individual whose pre-access test results are confirmed by the MRO as an FFD policy violation. Proposed §26.65(h)(1) and (h)(2) would cross-reference the relevant sanctions specified in proposed Subpart D [Management Actions and Sanctions] to clarify that those sanctions would apply to applicants for authorization. For example, if the MRO determines that an individual has submitted an adulterated urine specimen for a pre-access drug test, the licensee or other entity would be required to impose the sanction for an attempt to subvert the testing process (i.e., permanent denial of authorization) in proposed §26.75(b).

Proposed §26.65(h)(3) would be added to permit licensees and other entities to grant authorization to an individual whose confirmed non-negative test result is a first drug- or alcohol-related violation under a Part 26 program, consistent with current §26.27(b)(2).

However, the proposed rule would permit authorization to be granted only in accordance with the stringent requirements contained in proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information].

Section 26.67 Random drug and alcohol testing of individuals who have applied for authorization

A new §26.67 [Random drug and alcohol testing of individuals who have applied for authorization] would be added to extend current random testing requirements to individuals who have applied for authorization under Part 26 but to whom authorization has not yet been granted. The requirements contained the proposed section would be added to the access authorization requirements that were established by orders to nuclear power plant licensees dated January 7, 2003, for two reasons: (1) to enhance the effectiveness of FFD programs by increasing the likelihood that substance abuse would be detected before authorization is granted, and (2) to deter the potential for substance abuse among applicants.

A new §26.67(a) would require licensees and other entities to conduct random testing of applicants in accordance with the requirements of proposed §26.31(d)(2). That is, the licensee or other entity would add applicants to the FFD program's normal population of individuals who are subject to random testing, select individuals for testing at the 50 percent annual rate, and otherwise subject applicants to the same random testing requirements as individuals who currently hold authorization under Part 26. An applicant would be subject to random testing beginning when the licensee or other entity collects the specimens for any required pre-access test, and continuing thereafter, if the licensee or other entity grants authorization to the individual.

Licensees and other entities would be permitted to forego random testing of applicants in the two circumstances described in proposed §26.67(a)(1) and (a)(2). Proposed §26.67(a)(1) would permit a licensee or other entity to discontinue random testing of any applicant to whom the licensee or other entity does not grant authorization for any reason, including a termination or denial of authorization or a withdrawal of the application for authorization by the individual or the individual's employer, in the case of a C/V. Proposed §26.67(a)(2) would address the circumstance described in proposed §26.65(b), in which the licensee or other entity is permitted to meet pre-access testing requirements by relying upon negative test results from specimens collected under another Part 26 program within 30 days before granting authorization to the individual. Under proposed §26.67(a)(2), the licensee or other entity would begin subjecting the applicant to random testing when the licensee or other entity takes the first formal action to process the individual's application for authorization. The actions may include, but are not limited to, the point in time at which the licensee or other entity receives the individual's signed consent form and begins creating a record of the individual's application that would be accessible to other licensees and entities; conducts a psychological evaluation; begins a suitable inquiry; or takes other actions that are required under NRC regulations to grant authorization. The first formal action that the licensee or other entity takes to process an individual's application for authorization will vary, depending upon the licensee's FFD and access authorization program procedures, whether the applicant's FFD training is up-to-date, and other factors, which, together, make it impractical to establish in the proposed rule a single point in the authorization process at which random testing must begin. Therefore, the proposed paragraph would require the licensee or other entity to begin subjecting the individual to random testing when the licensee or other entity takes the first formal action, but would not define a specific formal action that would initiate random testing of applicants in all cases.

Proposed §26.67(b) would be added to permit licensees and other entities to grant authorization to an individual before random testing is completed, if the individual has met all of the requirements for authorization but has been selected for one or more random tests while in applicant status. That is, if the applicant has met all other applicable requirements for authorization, licensees and other entities need not delay granting authorization to the individual in order to conduct and obtain the results from a random test, if the applicant was selected for random testing while in applicant status. The proposed rule would not require the testing to be completed before the licensee or other entity grants authorization to the individual because the primary purpose of random testing of applicants would be to deter substance abuse rather than to provide information for the authorization decision. Pre-access testing provides the necessary information for authorization decision-making.

Proposed §26.67(c) would cross-reference the minimum sanctions to be imposed on an individual whose drug or alcohol test results from random testing are confirmed as non-negative. Proposed §26.67(c)(1) and (c)(2) would refer to the relevant sanctions specified in proposed Subpart D. Proposed §26.67(c)(3) would continue to permit licensees and other entities to grant authorization to an individual whose confirmed non-negative test result is a first drug- or alcohol-related violation under a Part 26 program, consistent with current §26.27(b)(2), but the proposed rule would permit authorization to be granted only in accordance with the stringent requirements contained in proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information].

Section 26.69 Authorization with potentially disqualifying fitness-for-duty information

A new §26.69 [Authorization with potentially disqualifying fitness-for-duty information] would replace and clarify the existing requirements contained in §26.27(b)(4), which establishes

requirements for granting authorization to an individual who has violated an FFD policy and had his or her authorization terminated unfavorably or denied for a period of 3 or 5 years under the current rule. Consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, the proposed section would be added to address problems that have arisen in implementing the current rule and clarify the NRC's intent with respect to several situations that are not addressed in the current rule.

Proposed §26.69(a) [Purpose] would be added to describe the purpose of the section and the applicants to whom the requirements in the proposed section would apply. The proposed rule would require licensees and other entities to meet the applicable requirements in this section before granting authorization to an individual or permitting an individual to maintain his or her authorization when potentially disqualifying FFD information is obtained about an individual through any means and the information has not been assessed and favorably resolved by a previous licensee or other entity. Proposed §26.63(b) would permit licensees and other entities to rely upon the results of determinations of fitness that were conducted by previous licensees or other entities, rather than requiring each new licensee or other entity to reevaluate the same information that was reviewed and resolved under another Part 26 program. However, if the potentially disqualifying FFD information was not previously reviewed and favorably resolved under another Part 26 program, licensees and other entities would implement the requirements contained in this proposed section.

The proposed paragraph would also revise the language contained in current §26.27(b)(2) to recognize that licensees and other entities may decide not to grant authorization to the subject individual and so, in that case, would not be required to implement these requirements. At the public meetings discussed in Section V, stakeholders noted that some individuals have misinterpreted the current rule as requiring licensees to provide individuals who

have violated an FFD policy with the opportunity to seek treatment for a substance abuse problem and to have authorization reinstated. However, although the NRC continues to affirm that individuals who pursue treatment and maintain sobriety may be considered for authorization, both the current and proposed rules assign the responsibility for making authorization decisions to the licensee or other entity. Therefore, the proposed paragraph would clarify that granting or maintaining the authorization of an individual about whom potentially disqualifying FFD information has been disclosed or discovered is "at the licensee's or other entity's discretion."

Proposed §26.69(b) [Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization] would be added to define requirements for granting authorization, at the licensee's or other entity's discretion, to an individual who had confirmed positive drug or alcohol test results and whose authorization, as a result, was previously terminated unfavorably or denied for 5 years. The requirements in the proposed paragraph would apply to: (1) an applicant who had a first confirmed positive test result on a pre-access test and was consequently denied authorization by a licensee; (2) an individual who is returning to duty following the 14-day assessment period required in current §26.26(b)(2), which would be moved to proposed §26.75(e)(1); (3) an individual whose authorization was terminated unfavorably under another Part 26 program and who had an interruption in authorization that was longer than 14 days; and (4) an individual whose authorization was denied for 5 years under the requirements of proposed §26.75(c), (d), (e)(2), or (f). The proposed paragraph would replace and strengthen the requirements contained in current §26.27(b)(2) and expand them to address confirmed positive alcohol test results, which are excluded from this process in current §26.27(b)(5). The proposed paragraph would include confirmed positive alcohol test results for the reasons discussed with respect to proposed §26.75(e).

Proposed §26.69(b)(1) would require the licensee or other entity to obtain and review a self-disclosure from the applicant to verify that it does not contain any previously undisclosed potentially disqualifying FFD information. Because the individual's last period of authorization was terminated unfavorably or denied, licensees and other entities would not be permitted to forego obtaining a self-disclosure and employment history under any circumstances, because it would be important to review the individual's activities during the interruption period. The period of time to be addressed in the self-disclosure would be the shorter of either the past 5 years or the intervening period since the individual last held authorization.

Proposed §26.69(b)(2) would increase the scope of the suitable inquiry that the licensee or other entity must conduct by requiring the licensee or other entity to conduct the suitable inquiry with every employer by whom the applicant claims to have been employed during the period of time addressed in the individual's self-disclosure. This extensive suitable inquiry would be necessary to determine whether any indications exist that the individual has continued to engage in substance abuse. The proposed rule would also required licensees and other entities to obtain and review any records that other licensees or entities may have developed related to any potentially disqualifying FFD information about the individual from the past 5 years. These records may include, but would not be limited to, the results of past suitable inquiries or other investigations, records of arrests or convictions, drug and alcohol test results, treatment records, and the results of determinations of fitness. This information would be used by the SAE to assess the individual's fitness and the licensee's or other entity's reviewing official to determine whether authorization is warranted.

Proposed §26.69(b)(3) would apply only to individuals whose authorization was denied for 5 years under the current rule or in accordance with §26.75(c), (d), (e)(2), or (f) of the proposed rule. The proposed paragraph would require the licensee or other entity to verify,

before granting authorization, that the individual had not abused alcohol or drugs during the 5-year interruption, at a minimum. The proposed requirement would be consistent with the portion of current §26.27(b)(4) that requires licensees to obtain "satisfactory medical assurance that the person has abstained from drugs for at least three years." However, the proposed rule would extend the requirement to 5 years to ensure that such an individual would be at the lowest risk of recidivism into an active substance abuse problem before the licensee or other entity could grant authorization to the individual.

Proposed §26.69(b)(4) would amend the requirement in current §26.27(b)(2), which mandates that an individual who has a first confirmed positive test result must be referred to the EAP for assessment and counseling before the licensee or other entity may grant authorization to the individual. The proposed paragraph would make several changes to the current provision. First, the proposed rule would replace the term, "management and medical assurance of fitness," which is used in current §26.27(b)(2) and (b)(4), with the term, "determination of fitness," to improve the accuracy of the language in the proposed rule. The proposed rule would not use "management" because the licensee's or other entity's reviewing official (see the discussion of proposed §26.69(c)(3) and the definition of "reviewing official" in proposed §26.5 [Definitions]) is the individual who licensees and other entities currently designate to make authorization decisions and the reviewing official may not be a manager. In addition, the proposed rule would permit professionals other than a licensed physician to conduct a determination of fitness, for the reasons discussed with respect to proposed §26.189 [Determination of fitness]. Therefore, this proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Consistent with the intent of the current requirement, the proposed paragraph would require the licensee or other entity to ensure that a "determination of fitness" is conducted, as

defined in proposed §26.189 [Determination of fitness], as part of the authorization decision. Proposed §26.187 [Substance abuse expert] would require that determinations of fitness that are conducted for authorization decisions must be performed by an SAE, whose role, responsibilities, and required qualifications would also be defined in proposed §26.187. Therefore, proposed §26.69(b)(4) would require that the individual must be referred to an SAE for a determination of fitness, but the proposed rule would not require the SAE to be an EAP employee. Permitting licensees and other entities to rely upon a professional who meets the required qualifications for an SAE, rather than only on EAP personnel, would more appropriately focus this requirement on assuring that the professional who performs the assessment and treatment planning is qualified, rather than on the professional's organizational affiliation.

Proposed §26.69(b)(4)(i)–(b)(4)(iii) would replace and strengthen the requirement in current §26.27(b)(2), which states that "any rehabilitation program deemed appropriate must be initiated during such suspension period." The proposed paragraph would require that the individual must be in compliance with or have successfully completed treatment plans, rather than simply started treatment, in order for the licensee or other entity to grant authorization to the individual and maintain the individual's authorization after it has been granted.

Proposed §26.69(b)(5) would be added to impose more stringent pre-access testing requirements on an individual who is being considered for authorization following an unfavorable termination or denial of authorization than those required for individuals whose last period of authorization was terminated favorably. The proposed paragraph would require negative results from an alcohol test performed within 10 business days before authorization is granted. Similarly, the proposed paragraph would require negative results from a urine specimen that was collected for drug testing within 10 business days before authorization is

granted, as well as collection of the urine specimen under direct observation. The proposed paragraph would prohibit the licensee or other entity from granting authorization to the individual before the drug test results are reported to the licensee's or other entity's MRO so that the MRO may determine whether the drug test results indicated that the individual has not engaged in any further drug abuse [see the discussion of proposed §26.69(f)]. Completing drug and alcohol testing within 10 days before granting authorization, rather than the 30 days that is permitted in proposed §26.65(f) [Time period for testing] for the other authorization categories, would provide evidence that the individual has abstained from abusing proscribed substances during the interruption period and that the individual would be able to safely and competently perform duties under this part when authorization is reinstated, if the individual's authorization has been interrupted for the 14-day assessment period required under current §26.27(b)(2) and retained in proposed §26.75(e)(1). Requiring direct observation of the urine specimen collection would be necessary to provide added assurance that the specimen is valid and yields accurate drug test results.

Proposed §26.69(b)(6) would apply only to individuals whose authorization has been unfavorably terminated or denied for at least 14 days for a first confirmed positive drug or alcohol test result. The proposed paragraph would replace the third sentence of current §26.27(b)(4), which establishes requirements and a schedule for followup drug and alcohol testing for an individual whose authorization was denied for 3 years under the current rule, and apply the requirement for followup testing to individuals who have had a first confirmed positive test result for drugs or alcohol. The proposed requirement would provide greater deterrence of further drug and alcohol use than current §26.27(b)(4), which requires this followup testing only for the more serious FFD violations that result in a denial of authorization for 3 years or longer.

The more stringent requirement would provide higher assurance that individuals who are subject to this part are trustworthy, reliable, and fit for duty.

Proposed §26.69(b)(6) would amend the current fixed schedule for followup testing by requiring licensees and other entities to subject the individual to the possibility of being selected for followup testing, during any period in which he or she holds authorization under Part 26, for a period of 3 calendar years after the individual's authorization is restored following termination or denial for the first confirmed positive drug or alcohol test result. The proposed rule would require licensees and other entities to ensure that the individual is subject to unannounced testing at least 15 times within the 3-year period and verify that the individual's test results are negative. Either random or followup tests, which are both unannounced, may be used to meet this proposed requirement. The proposed rule would require licensees and other entities to distribute the unannounced tests over the 3-year period, with at least one unannounced test conducted each quarter.

Proposed §26.69(b)(6)(i)–(b)(6)(iii) would be added to address circumstances in which an individual is not continuously subject to a Part 26 program during the 3 years following restoration of authorization. Proposed §26.69(b)(6)(i) would require that an individual who intermittently holds authorization over the 3-year period must be subject to unannounced testing at least once in each quarter during which the individual is authorized. Proposed §26.69(b)(6)(ii) would permit the licensee or other entity to extend the followup testing period to 5 years, if the requirement for 15 tests over the 3-year period has not been met because the individual has not been authorized a sufficient number of times or for sufficient periods of time during the first 3 years to meet the proposed 15-test requirement. Proposed §26.69(b)(6)(iii) would permit the licensee or other entity to have an SAE conduct a determination of fitness to

determine whether further followup testing is required, if an individual is unable to meet the 15-test requirement after 5 years due to brief and infrequent periods of authorization.

These proposed changes to the current followup testing requirements respond to information provided by stakeholders in the public meetings discussed in Section V. Stakeholders reported that some individuals who are subject to followup testing have been unable to satisfy the requirements of current §26.27(b)(4) because they are not continuously employed in the nuclear industry in job positions that require authorization, and, therefore, are not continuously subject to a Part 26 FFD program. As a result, these individuals have been unable to demonstrate negative test results on tests that are performed "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." Stakeholders reported that some individuals have been unable to satisfy the current requirement after 10 years, despite obtaining negative test results on every pre-access, random, and followup test administered during that period, because the individuals were not continuously subject to a Part 26 followup testing program for the required 3-year period. This was not the intent of the current provision. Therefore, the proposed revision to this requirement would increase the flexibility with which licensees and other entities may implement followup testing requirements, but retain the current effectiveness of followup testing in detecting and deterring substance abuse.

Proposed §26.69(b)(7) would be added to require the licensee or other entity to verify that the results of all drug and alcohol tests that are administered to the individual under a Part 26 program following restoration of the individual's authorization indicate no further drug or alcohol abuse. The proposed paragraph would not specify that the drug test results must be negative, because the metabolites of some drugs, such as marijuana, may be present in an individual's urine for several weeks after the individual has stopped using the drug. If an

individual is tested again soon after the original test that resulted in an FFD violation was conducted, the specimen may yield positive results which would not, in fact, reflect new drug use. Therefore, if subsequent drug test results show the presence of the same drug or drug metabolites in the individual's urine as detected in the original confirmed positive test result, the MRO, under proposed §26.185(o), would be required to determine whether the results indicate new drug use or are consistent with results that would be expected from the drug use that resulted in the previous confirmed positive test result. The proposed rule would add this requirement in response to inconsistencies in the manner in which some MROs have implemented current requirements related to return-to-duty drug testing. Some MROs have been inappropriately reluctant to declare a second drug test result as negative if any concentration of the drug or drug metabolites that resulted in a first confirmed positive drug test result are detected in the specimen. The proposed change would permit an individual who has not engaged in further drug use after a first confirmed positive drug test result to regain authorization, at the licensee's discretion, rather than be incorrectly denied authorization for 5 years on the basis of a subsequent FFD policy violation, under proposed §26.75(e)(2).

Proposed §26.69(c) [Granting authorization with other potentially disqualifying FFD information] would be added to establish requirements for granting authorization to an individual about whom potentially disqualifying FFD information is discovered or disclosed that was not a confirmed non-negative drug or alcohol test result or 5-year denial of authorization. For example, this type of potentially disqualifying FFD information may include, but would not be limited to: (1) a report of an arrest for an alcohol-related traffic violation; (2) information from the suitable inquiry that an individual's employment was terminated by a previous private-sector employer because of drug- or alcohol-related job performance problems; or (3) information obtained from the suitable inquiry or other sources of information indicating that the individual is

known to abuse illegal drugs or alcohol or is experiencing significant mental or emotional stress. The proposed paragraph would be necessary because the current rule does not address the authorization process in such circumstances and the NRC is aware that licensees and other entities have handled these circumstances inconsistently. Therefore, the proposed rule would add these requirements to establish the NRC's intent with respect to these circumstances and increase consistency between Part 26 programs.

Proposed §26.69(c)(1) would be added to require the licensee or other entity to verify that the individual's self-disclosure addresses the applicable period specified in proposed §26.61(b)(3). The proposed rule would not require the licensee or other entity to "obtain" a self-disclosure in all circumstances, because the individual may have already provided a self-disclosure under proposed §§26.55, 26.57, or 26.59 and an additional self-disclosure and employment history would be unnecessary.

Proposed §26.69(c)(2) would require the licensee or other entity to conduct a suitable inquiry with every employer for the period that would be addressed in the self-disclosure and employment history. If the potentially disqualifying FFD information was identified during the course of conducting a suitable inquiry in accordance with proposed §26.63(f) so that the suitable inquiry was partially completed, proposed §26.69(c)(3) would require the licensee or other entity to conduct a more complete suitable inquiry by contacting every employer that the individual listed during the interruption period. The proposed paragraph would also require the licensee or entity to obtain and review any records that other licensees or entities who are subject to this part may have developed with regard to potentially disqualifying FFD information about the individual from the past 5 years. This more complete suitable inquiry would be necessary to ensure that the licensee or other entity has more information about the individual

than is required for individuals whose last period of authorization was terminated favorably in order to make an appropriate authorization decision.

Proposed §26.69(c)(3) would be added and would use the term, “reviewing official,” to refer to the employee who is designated by the licensee or other entity to make authorization decisions, as discussed with respect to proposed §26.5 [Definitions]. The proposed paragraph would permit the reviewing official to grant or deny authorization, based upon his or her review of the circumstances associated with the potentially disqualifying FFD information. Because of the variety of circumstances that may arise, the proposed paragraph also would grant discretion to the reviewing official in deciding whether a determination of fitness is required, rather than requiring a determination of fitness in every case. However, if the reviewing official requests a determination of fitness and the professional who performs it recommends any form of treatment or drug and alcohol testing, including the collection of urine specimens under direct observation, proposed §26.69(c)(4) would require the licensee or other entity to implement the treatment and testing recommendations.

Proposed §26.69(c)(5) would be added to require pre-access and random testing of the applicant for authorization. The proposed paragraph would require the licensee or other entity to verify that the results of pre-access drug and alcohol tests are negative before granting authorization to the individual. The proposed rule would require the licensee or other entity to verify that test results are negative before granting authorization to the individual to provide evidence that the individual is avoiding substance abuse.

Proposed §26.69(d) [Maintaining authorization with other potentially disqualifying FFD information] would be added to establish requirements for maintaining an individual’s authorization when new potentially disqualifying FFD information is disclosed or discovered that was not a confirmed non-negative drug or alcohol test result or 5-year denial of authorization, if

the reviewing official determines that maintaining authorization is warranted. A self-disclosure, suitable inquiry, and pre-access testing would not be required because the individual would not be applying for authorization. However, the proposed paragraph would require the reviewing official to review the circumstances related to the information, and, at his or her discretion, ensure that a professional with the appropriate qualifications makes a determination of fitness. The proposed paragraph would require the licensee or other entity to implement any treatment or testing requirements resulting from the determination of fitness. The proposed paragraph would be added because the current rule does not address maintaining an individual's authorization in such circumstances and the NRC is aware that licensees and other entities have handled these circumstances inconsistently. Therefore, the proposed rule would add these requirements to establish the NRC's intent with respect to these circumstances and increase consistency between Part 26 programs

A new §26.69(e) [Accepting followup testing and treatment from another Part 26 program] would establish continuity of care requirements for individuals who were subject to a followup testing and substance abuse treatment plan under one Part 26 program and transfer to another FFD program or leave and then return to the same FFD program. The proposed paragraph would require the receiving licensee other entity to continue the testing and treatment plan to which the individual was subject under the previous FFD program. The proposed rule would also permit the receiving licensee or other entity to accept and rely upon any followup testing that was completed while the individual was subject to the previous Part 26 program in determining how long followup testing must continue. For example, if an individual met all of the requirements for authorization by a new licensee, but had completed only 2 of the 3 years of followup testing required under a previous Part 26 program, then the granting licensee would administer the final year of the followup testing, but would not be required to "re-

start the clock" and conduct another 3 full years of followup testing after the individual was authorized. If the transferring individual successfully completed any followup testing and treatment program required under the first FFD program, a previous determination of fitness indicated that the individual is fit for duty, and the individual's authorization by the first licensee or other entity was terminated favorably, then the proposed paragraph would permit the receiving licensee or other entity to accept the previous determination of fitness and would not require the granting licensee to develop and implement an additional testing and treatment plan.

Proposed §26.69(f) [Sanctions for confirmed non-negative drug and alcohol test results] would be added to clarify the minimum sanctions to be imposed on an individual who has confirmed non-negative drug and alcohol test results on any tests that may be required under this proposed section. Proposed §26.69(f)(1) and (f)(2) would cross-reference the relevant sanctions specified in proposed Subpart D [Management actions and sanctions] to establish that those sanctions would apply to individuals about whom potentially disqualifying FFD information has been discovered or disclosed.

Section 26.71 Maintaining authorization

Proposed §26.71 [Maintaining authorization] would be added to state the requirements for maintaining authorization under this part. The proposed section would respond to stakeholder requests for this clarification at the public meetings discussed in Section V.

Proposed §26.71(a) would provide that individuals may maintain authorization under the conditions listed in proposed §26.71(a)(1)–(a)(4), as follows:

Proposed §26.71(a)(1) would establish that an individual must comply with the licensee's or other entity's FFD policies to which the individual is subject. This proposed requirement thus relates, although it does not refer, to proposed §26.27 [Written policy and procedures], which would require the licensee or other entity to prepare a clear and concise statement of its FFD policy and make that policy readily available to all individuals who are subject to it. The proposed rule would require that all individuals who are subject to the FFD policy must have information on what is expected of them and what consequences may result from a lack of adherence to the policy. Proposed §26.71 would also require that, in order to maintain authorization, an individual must report any legal actions, as defined in proposed §26.5 [Definitions]. Finally, although not explicitly specified in proposed §26.71(a)(1), proposed §26.33 [Behavioral observation] would require individuals to report any FFD concern to the personnel designated in the FFD policy.

Proposed §26.71(a)(2) would establish that an individual may maintain authorization if the individual remains subject to a drug and alcohol testing program that complies with the requirements of Part 26, including random testing. Licensees and other entities who are subject to Part 26 are responsible for implementing drug and alcohol testing programs that comply with the requirements in proposed §26.31 [Drug and alcohol testing], and the failure of a licensee or other entity to maintain a program would terminate the authorizations of individuals who have been granted authorization by the licensee or other entity. [See the discussion of §26.71(b).] In addition, proposed §26.31 also would place certain responsibilities on individuals who are subject to the testing program. In particular, under proposed §26.31(d)(2)(iii), individuals who are selected for random testing would be required to report to the collection site as soon as reasonably practicable after notification, and within the time period specified in FFD program procedures, as well as to cooperate in the testing process. In appropriate

circumstances, an individual's failure to report or cooperate could be the basis for terminating the individual's authorization.

Proposed §26.71(a)(3) would establish that an individual may maintain authorization if the individual remains subject to a behavioral observation program that complies with the requirements of Part 26. Behavioral observation, as required by proposed §26.33 [Behavioral observation], would be performed by individuals, including coworkers, who have been trained to detect behaviors that may indicate possible use, sale, or possession of illegal drugs; use or possession of alcohol on site or while on duty; or impairment from fatigue or any cause that, if left unattended, might constitute a threat to the health and safety of the public or the common defense and security.

Proposed §26.71(a)(4) would establish that a condition for maintaining authorization is successful completion by the individual of required FFD training, according to the schedule in proposed §26.29(c). As specified in proposed §26.29(c)(1), the proposed rule would require the individual to complete training before the licensee or other entity grants initial authorization. Thereafter, as specified in proposed §26.29(c)(2), the proposed rule would require individuals to complete refresher training or pass a comprehensive examination on a nominal 12-month frequency. Proposed §26.29(d) would provide that licensees and other entities may accept training of individuals who have been subject to another Part 26 program and have, within the past 12 months, either had initial or refresher training or successfully passed a comprehensive examination that meets the requirements of proposed §26.29.

Proposed §26.29(d) would require a licensee or other entity to terminate an individual's authorization if the individual, for more than 30 [consecutive] days, is not subject to an FFD program that meets the requirements of Part 26. The requirements of the proposed paragraph would permit an individual to be away from all elements of a Part 26 program for this period of

time in order to accommodate vacations and significant illnesses when the individual would not be reasonably available for behavioral observation or to collect specimens for random drug and alcohol testing. The proposed paragraph would be added in response to stakeholder requests and would be consistent with related requirements in the access authorization orders issued to nuclear power plant licensees on January 7, 2003.

Subpart D – Management Actions and Sanctions

Section 26.75 Sanctions

The first sentence of proposed §26.75(a) would introduce the purpose of the section, which would be to define the minimum sanctions that licensees and other entities must impose when an individual has violated the drug and alcohol provisions of an FFD policy. The second sentence of the proposed paragraph would restate the second sentence of current §26.27(b), which permits licensees and other entities to impose more stringent sanctions than those specified in the rule. The proposed rule would add a reference to paragraph (h) of the proposed section, which would establish limits on the sanctions that licensees and other entities may impose for non-negative validity and drug test results, to clarify that there is one exception to the blanket permission to impose more stringent sanctions granted in this paragraph, as discussed with respect to proposed paragraph (h) of this section. These proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.75(b) would be added to require licensees and other entities to permanently deny authorization to individuals who refuse to be tested or who in any way subvert or attempt to subvert the testing process. The proposed sanction is necessary because

acts to subvert the testing process reflect a sufficiently egregious lack of trustworthiness and reliability to warrant permanent denial of authorization. An individual's willingness to subvert or attempt to subvert the testing process provides strong evidence that the individual will also be willing to disregard other rules and regulations, such as safeguards requirements, which ensure the protection of public health and safety and the common defense and security. In addition, if an individual succeeds in subverting the testing process in order to hide substance abuse, the individual may pose an undetected and unacceptable risk to public health and safety or the common defense and security by performing the duties that require him or her to be subject to this part while impaired. Therefore, the proposed change would be made to meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs, by deterring acts to defeat the testing process as well as preventing any individuals who engage in them from posing any further risk to public health and safety and the common defense and security

The proposed rule would specify three examples of actions that would be considered subversion or an attempt to subvert the testing process. These include refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen. However, these examples are not intended to be exhaustive. For example, if a licensee or other entity determines that several individuals had colluded to notify potential donors that they would be selected for random testing on a particular day, so that the potential donors could plan to avoid work on that day or take other actions to ensure that their illegal drug use would not be detected, the NRC would expect the licensee or other entity to permanently deny authorization to all of the individuals who were involved in the collusion.

The proposed rule would not include submitting a dilute specimen as an example of a subversion attempt without additional evidence that the donor had diluted the specimen in order to mask the presence of drugs or drug metabolites in the specimen, for the reasons discussed

with respect to proposed §26.185(g). Submitting a dilute specimen, in itself, would not necessarily indicate an attempt to subvert the testing process because there are many legitimate causes for a dilute specimen, including drinking liquids in order to provide a specimen of sufficient quantity, as permitted in Section 2.4(g)(11) in Appendix A of the current rule and in proposed §26.109(b)(1). Therefore, the proposed rule would not require licensees and other entities to apply the sanction of permanent denial of authorization for submitting a dilute specimen, unless there is other evidence that the donor had diluted the specimen in an attempt to subvert the testing process.

The phrase, "for any test required under this part," would be added to proposed §26.75(b) to indicate that applicants for authorization who subvert or attempt to subvert a pre-access or random test would also be subject to permanent denial of authorization. Although these individuals would not yet be performing any job duties that could affect public health and safety or the common defense and security, an attempt to subvert the testing process while in an applicant status provides strong evidence that the individual cannot be trusted to perform those job duties. Therefore, it is necessary to ensure that any applicant who subverts or attempts to subvert the testing process would be denied authorization.

Proposed §26.75(c) would amend current §26.27(b)(3), which establishes sanctions for the sale, use, or possession of illegal drugs within a protected area of any nuclear power plant, within a facility that is licensed to possess or use formula quantities of SSNM, or within a transporter's facility or vehicle. The proposed paragraph would retain the current sanction of a 5-year denial of authorization in these instances and add two other instances in which a 5-year denial of authorization would be required.

First, the proposed rule would require licensees and other entities to impose a 5-year denial of authorization on any individual who is determined to have consumed alcohol within a

protected area of any nuclear power plant, within a facility that is licensed to possess or use formula quantities of SSNM, or within a transporter's facility or vehicle. This proposed change is necessary because consuming alcohol causes impairment, which poses the same risks to public health and safety as impairment from illegal drugs. Extending the scope of the current sanction to alcohol consumption also would be consistent with the revised FFD program performance objective in proposed §26.23(d), which is to provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of alcohol as well as illegal drugs. Therefore, the proposed change would be made to meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs, by reducing the risk to public health and safety and the common defense and security that on-site use of alcohol poses.

Second, the proposed rule would add the phrase, “or while performing the job duties that require the individual to be subject to this part,” to address circumstances in which an individual may be performing job duties that require him or her to be subject to this part but is not performing those duties within the protected area of a nuclear power plant, within a facility that is licensed to possess or use formula quantities of SSNM, or within a transporter's facility or vehicle. As one example, many nuclear power plant licensees’ designated collection sites are located outside of the plant’s protected area. The intent of the current rule is to prohibit the presence, sale, and use of alcohol or illegal drugs by FFD program personnel at a collection site that is located outside of the protected area, but the current rule does not specifically address such circumstances. The majority of licensees have appropriately interpreted the intent of the current rule, but the proposed rule would add this phrase to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

In addition, the list of activities in the current paragraph that an individual would be prohibited from performing would be deleted in the proposed paragraph and replaced with the summary term, “authorization,” for consistency with the use of this term throughout the proposed rule. As discussed with respect to proposed §26.25 [Individuals subject to the fitness-for-duty program], the list of job duties that require individuals to maintain authorization and to be subject to this part would be presented once in proposed §26.25, rather than repeatedly throughout the rule, for consistency with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.75(d) would amend the portion of current §26.27(c) that requires licensees to record as a removal “for cause” an individual’s resignation that occurs before the licensee “removes” the individual for violating the FFD policy. This portion of the current provision has raised implementation questions from licensees regarding the appropriate action to take in these circumstances. Licensees have questioned whether the intent of the current requirement is to deny authorization to an individual for some period of time, as required under current §26.27(b)(2)–(b)(4), permanently deny authorization to the individual, or merely to record the resignation. Therefore, the proposed rule would clarify the intent of the current provision, as follows:

The proposed rule would establish the sanction of a 5-year denial of authorization for an individual who resigns before a licensee or other entity terminates the individual’s authorization or denies authorization to an applicant for a first violation of the FFD policy involving a confirmed positive drug or alcohol test result. The proposed paragraph would establish a 5-year denial of authorization because the confirmed positive drug or alcohol test result, in combination with such a resignation, would be a strong indication that the individual has an active substance abuse problem. However, because the individual resigned or withdrew his or

her application for authorization, the individual would not be available for the SAE to evaluate the seriousness of his or her substance abuse problem and devise an appropriate treatment plan, as required under proposed §26.189 [Determination of fitness]. Therefore, prohibiting the individual from being granted authorization for a 5-year period would give the individual an opportunity to seek treatment and establish a 5-year history of sobriety, which would be required to regain authorization under proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information], while also ensuring that such an individual is not granted authorization without having demonstrated that he or she has overcome the substance abuse problem.

In addition, for any type of FFD policy violation, the proposed paragraph would require the licensee or other entity to record the fact that the individual had resigned or withdrawn his or her application for authorization, the nature of the FFD policy violation, and the sanction that would have been imposed if the individual had not resigned or withdrawn. Recording this information would be necessary to ensure that any licensees or other entities who may consider granting authorization to the individual in the future would be aware of the individual's behavior and the nature of the FFD policy violation. Subsequent licensees and other entities would then be able to ensure that the minimum requirements of this section are met. For example, if the FFD policy violation was a third confirmed positive drug or alcohol test result, proposed §26.75(g) would prohibit a subsequent licensee or other entity from granting authorization to the individual under any circumstances.

The portion of current §26.27(c) that refers to a refusal to provide a specimen for testing would be moved to proposed §26.75(b) for organizational clarity, as discussed with respect to that paragraph.

Proposed §26.75(e) would amend current §26.27(b)(2) and expand its scope to include alcohol. Abuse of alcohol would no longer be excluded from the sanctions specified in this proposed section for several reasons. First, although the possession and use of alcohol are legal for adults and do not adversely reflect on an individual's trustworthiness and reliability, a perceived need to conceal an untreated, active alcohol abuse problem could cause an individual to be vulnerable to influence to act in ways that are adverse to the common defense and security. Second, alcohol-related impairment in the nuclear workplace poses an undue potential risk to public health and safety that is comparable to the risk imposed by impairment from the use of drugs. Third, some licensees have not imposed appropriately stringent sanctions on individuals who have abused alcohol in a manner that could cause the individual to be impaired while performing the job duties that require individuals to be subject to this part. Therefore, in order to deter individuals from abusing alcohol and ensure that individuals who may be impaired from alcohol are not permitted to perform job duties under this part, the proposed rule would impose the same sanctions for abusing alcohol as those required for abusing drugs in the proposed paragraph. The proposed change would be made to meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs.

Proposed §26.75(e)(1) would retain the intent of the second sentence of current §26.27(b)(2), which states that licensees and other entities must remove an individual from performing activities under this part for at least 14 days following a first confirmed positive test result. However, the proposed paragraph would require licensees and other entities to terminate the individual's authorization for at least 14 days, rather than "remove" the individual. At the public meetings discussed in Section V, the stakeholders indicated that the term, "remove," is confusing because it could be interpreted as requiring licensees and other entities to terminate the individual's employment, which is not the intent of this paragraph. The

stakeholders suggested using the phrase, “terminate the individual’s authorization,” to more accurately characterize the required action, with which the NRC concurred.

The stakeholders also requested that the requirements in the current paragraph related to referring the individual to the EAP for assessment and counseling be eliminated from proposed §26.75(e)(1). The stakeholders noted that many licensees terminate an individual’s employment at the same time that they terminate the individual’s authorization after a first confirmed positive test result. They suggested that, if the licensee or other entity terminates the individual’s employment and does not intend to provide the individual with an opportunity to regain authorization, it is inappropriate to require the licensee or other entity to provide assessment and counseling services to the individual. However, some licensees have interpreted the current provision as requiring them to provide EAP services to individuals who are no longer in their employ. The NRC concurs that the intent of the current rule is for licensees and other entities to provide assessment and counseling services only in those instances in which the licensee or other entity desires to reinstate the individual’s authorization. Therefore, the proposed change would be made to clarify the intent of the provision.

The proposed rule would also move the requirements in the current paragraph that are related to permitting the individual to regain authorization from this section to proposed Subpart C [Granting and Maintaining Authorization], because this section would address sanctions for FFD policy violations, rather than FFD requirements for granting authorization. Requirements for granting authorization to an individual after his or her authorization has been terminated unfavorably for a first confirmed positive drug or alcohol test result would be addressed in proposed §26.69(b) [Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization] of proposed Subpart C. This proposed change would be made for organizational clarity in the rule.

Proposed §26.75(e)(2) would increase the length of the period for which licensees and other entities must deny an individual's authorization for a second confirmed positive test result from 3 years in current §26.27(b)(vii) to 5 years. This proposed change would be made to provide higher assurance that individuals who have had a second confirmed positive test result are able to abstain from substance abuse for at least 5 years before a licensee or other entity may again consider granting authorization to them. The 5-year period is based upon the research literature indicating that individuals who abstain from substance abuse for 5 years after treatment are less likely to relapse than individuals who have been able to abstain for 3 years. In addition, the proposed more stringent sanction for a second confirmed positive test result would provide greater deterrence to recidivism than the current 3-year period.

Proposed §26.75(f) would amend current §26.27(b)(5), which states that the sanctions for confirmed positive drug test results in current §26.27 do not apply to the misuse of alcohol, valid prescriptions, and over-the-counter drugs, but requires licensees' FFD policies to establish sanctions that are sufficient to deter misuse of those substances. The proposed rule would require the same minimum sanctions for alcohol abuse as those required for drug abuse. Impairment caused by alcohol abuse creates a risk to public health and safety that is fundamentally similar to the risk posed by the use of illegal drugs. Some licensees, however, have imposed lesser sanctions for alcohol violations, an approach that is inconsistent with the NRC's intent. Therefore, the proposed rule would rectify this situation by explicitly requiring the same minimum sanctions for abuse of alcohol as currently required for the use of illegal drugs.

In addition, proposed §26.75(f) would require licensees and other entities to impose the same sanctions as required for abuse of illegal drugs if the MRO determines that misuse of prescription drugs or over-the-counter medications that results in a positive drug or alcohol test result represents substance abuse. The MRO would make this determination in accordance

with proposed §26.185(j). Misuse of prescription and over-the-counter medications may include, for example, the use of a spouse's or other family member's prescription medications that may cause impairment, such as some pain relievers, or the excessive use of some cold and cough preparations available over-the-counter containing alcohol or other active ingredients that may cause impairment. However, the same substances may be used by an individual who has a substance abuse problem. For example, an individual who has become addicted to opiates may use a spouse's or other family member's codeine tablets or other opiates that were prescribed for pain relief to assist the addicted individual in avoiding withdrawal symptoms. Under the proposed paragraph, if the MRO determines that an individual's use of a prescription or over-the-counter medication represents substance abuse, the licensee or other entity would be required to impose the minimum sanctions specified in this proposed section for a confirmed positive drug or alcohol test result, as appropriate. If the MRO determines that the misuse of a prescription or over-the-counter medication does not represent substance abuse, the proposed rule would require the licensee or other entity to impose the sanctions for substance misuse that the licensee or entity would specify in the FFD policy.

The proposed rule would also revise but retain the requirement in the last sentence of current §26.27(b)(5), which states that sanctions for the misuse of prescription and over-the-counter drugs must be sufficient to "deter abuse of legally obtainable substances." These sanctions must be sufficient to deter the misuse of prescription and over-the-counter medications because such misuse may lead to impairment on the job. However, the proposed rule would eliminate the phrase, "as a substitute for abuse of proscribed drugs," in the last sentence of current §26.27(b)(5) because it unnecessarily limits the circumstances in which sanctions for the misuse of prescription and over-the-counter drugs would be imposed.

Proposed §26.75(g) would amend current §26.27(b)(4). The portions of the current paragraph that establish requirements for granting authorization to an individual who has violated the licensee's or other entity's FFD policy would be moved to proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information] in Subpart C [Granting and Maintaining Authorization] for organizational clarity because proposed §26.75(g) would only address sanctions for FFD policy violations. The proposed paragraph would retain the portion of the current paragraph that requires licensees and other entities to permanently deny authorization to an individual who has repeatedly violated a licensee's or other entity's FFD policy. The proposed rule would require an individual's authorization to be denied permanently if he or she has another confirmed positive drug or alcohol test result after he or she has had authorization denied for 5 years in accordance with other paragraphs in this proposed section. This proposed more stringent sanction would strengthen the effectiveness of the rule in providing high assurance that individuals who are subject to this part are trustworthy and reliable, as demonstrated by avoiding substance abuse, and by increasing the assurance that only individuals who are fit for duty are permitted to perform the job duties listed in proposed §26.25 [Individuals subject to the fitness-for-duty program].

Proposed §26.75(h) and (i) would amend current §26.24(d)(2), which permits licensees to temporarily suspend an individual's authorization or take other administrative action if an individual has a positive drug test result for marijuana or cocaine metabolites that is identified through initial testing at the licensee testing facility. For organizational clarity, the proposed rule would divide the current paragraph into two paragraphs to separate the requirements related to the conditions under which licensees and other entities may and may not take action on the basis of initial test results.

Proposed §26.75(h) would continue to prohibit licensees and other entities from taking administrative actions or imposing sanctions on an individual based on an positive initial drug test result reported by an HHS-certified laboratory. The proposed paragraph would also continue to permit licensees and other entities to take administrative actions on the basis of positive initial drug test results for marijuana and cocaine from a licensee testing facility. However, in order for the licensee or other entity to take action, the proposed rule would require that the urine specimen that yields a non-negative drug test result(s) must also appear to be a valid specimen, based upon the results of validity screening or initial validity test results at the licensee testing facility. In addition, the proposed paragraph would prohibit licensees and other entities from imposing sanctions or taking other actions in response to non-negative validity screening or initial validity test results from a specimen in which no drug metabolites were detected. This proposed prohibition would be added because the procedures, instruments, and devices used in conducting validity screening and initial validity tests have not yet been proven to be sufficiently accurate and reliable to support management actions or sanctions without confirmatory testing. Permitting licensees and other entities to take actions on the basis of validity screening or initial validity test results would risk imposing substantial burdens on individuals from false non-negative test results. Therefore, this prohibition would be added to meet Goal 7 of this rulemaking, which is to protect the due process rights of individuals who are subject to Part 26.

Proposed §26.75(i)(1)–(4) would retain the requirements in current §26.24(d)(2)(i)–(iv) that establish the conditions under which licensees and other entities may take administrative actions on the basis of a positive initial drug test result for marijuana or cocaine metabolites from a licensee testing facility. The proposed rule would add a requirement for specimen validity testing (see the discussion of proposed §26.31(d)(3)(i) with respect to the addition of

validity testing requirements in the proposed rule) and require that the specimen for which action will be taken must appear to be valid, based on validity screening or initial validity test results from the licensee testing facility. The proposed rule would also revise the terminology used in the current paragraph to be consistent with the terminology used throughout the proposed rule (see the discussion of proposed §26.5 [Definitions] with respect to the new terminology adopted in the proposed rule) and update the cross-references to other sections of the rule to be consistent with the organization of the proposed rule.

Section 26.77 Management actions regarding possible impairment

A new §26.77 [Management actions regarding possible impairment] would amend the requirements of current §26.27(b)(1). The current paragraph requires licensees and other entities to remove impaired workers, or those whose fitness may be questionable, from performing activities within the scope of this part, and permits them to return the individuals to duty only after the individuals are determined to be fit to safely and competently perform their duties. The proposed section would retain the intent of the current provision, but the terminology used in the proposed section would be revised to be consistent with the terminology used throughout the proposed rule. Cross-references to other sections of the rule would be updated to be consistent with the organization of the proposed rule. In addition, several new requirements would be added.

Proposed §26.77(a) would be added to describe the purpose of the proposed section, which is to prescribe the management actions that licensees and other entities must take when an individual shows indications that he or she is not fit to safely and competently perform the duties that require the individual to be subject to this part. The proposed paragraph would be

added to introduce the section and to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.77(b) would retain the portion of current §26.27(b)(1) that requires the licensee or other entity to take immediate action to prevent an individual from performing the job duties that require the individual to be subject to this part if an individual appears to be impaired, or his or her fitness is questionable. The proposed paragraph would add cross-references to proposed §26.27(c)(3), and §26.199(h) and (i), because the proposed provisions would provide exceptions to the requirement for immediate action. Proposed §26.27(c)(3) would permit licensees and other entities to use individuals who have consumed alcohol if they are needed to respond to an emergency and the licensee or other entity establishes controls and conditions under which the individual may perform work safely. Proposed §26.199(h) and (i) would also permit licensees who are subject to proposed Subpart I [Managing Fatigue] to use fatigued individuals to perform work if the licensee determines that they are needed to protect the common defense and security or respond to an emergency and establishes controls and conditions under which the individual may perform work safely. The cross-references would be added to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

The proposed rule would also revise some terminology used in the current paragraph in response to stakeholder requests during the public meetings discussed in Section V. The stakeholders indicated that, because the current rule requires them to “remove” individuals whose fitness may be questionable, some FFD programs have interpreted the current paragraph as requiring them to terminate the individual’s authorization. This was not the intent of the current provision. In this instance, the intent of the rule was for licensees and other entities to prevent the individual from performing the job duties that would require the individual

to be subject to this part in order to ensure that any potential impairment could not result in errors or lapses in judgment that may pose a risk to public health and safety or the common defense and security until the cause of the problem could be identified and resolved. Therefore, the proposed rule would replace the phrase, “removed from activities within the scope of this part,” with the phrase, “prevent the individual from performing the job duties,” and make other minor changes to the wording of the current requirement to clarify the intent of the provision. The proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

Proposed §26.77(b)(1) would retain the intent of current §26.24(a)(3), which requires licensees and other entities to conduct drug and alcohol testing for cause. The proposed rule would require for-cause testing based upon a “reasonable suspicion” that the individual may be impaired from possible substance abuse. Reasonable suspicion of substance abuse could be based upon an observed behavior, such as unusual lack of coordination or slurred speech, or a physical condition, such as the smell of alcohol. If the only basis for a reasonable suspicion is the smell of alcohol, then alcohol testing would be required, but the proposed rule would not require the licensee or other entity to perform a drug test unless other indicators of possible impairment are present.

The proposed rule would not require drug testing without other indicators of impairment in response to stakeholder comments made during the public meetings discussed in Section V. The stakeholders reported that many of the for-cause tests they perform are initiated as a result of a security officer or other person reporting that an individual smells of alcohol without behavioral indications of impairment. They also noted that the very large majority of the for-cause drug tests that they conduct in these circumstances yield negative results, including those instances in which the alcohol test results are positive. The stakeholders suggested that

the current requirement to conduct drug tests in these circumstances imposes a significant burden because the drugs tests impose costs, not only for collecting and testing the urine specimens, but also because they cannot permit the individual to resume performing his or her job duties until the drug test results are available, which may take several days. The stakeholders argued that the burden is unnecessary because the drug tests yield positive results so infrequently and, therefore, do not serve their intended purpose of detecting drug abuse. Based on the stakeholders arguments and the FFD program performance data that support them, the NRC concurs that drug testing is unnecessary when the smell of alcohol is the only indication that for-cause testing is required, and so would eliminate it from the proposed rule. The proposed rule would continue to require drug testing if there are behavioral or physical indications of impairment in addition to the smell of alcohol.

Proposed §26.77(b)(2) would be added but would apply only to nuclear power plant licensees who would be subject to proposed Subpart I [Managing Fatigue]. The proposed paragraph would permit these licensees to forego drug and alcohol testing and a determination of fitness, if the licensee is certain that the individual's observed behavior or physical condition is solely due to fatigue. In this case, the proposed rule would require the licensee to conduct a fatigue assessment, as defined in proposed §26.201 [Fatigue assessments], before permitting the individual to return to performing his or her job duties.

Proposed §26.77(b)(3) would be added to specify the actions that licensees and other entities must take when there are indications that an individual may be impaired, other than behavior or a physical condition that creates a reasonable suspicion of substance abuse (or fatigue, in the case of licensees who are subject to proposed Subpart I). Consistent with current §26.27(b)(1), the proposed rule would permit the licensee or other entity to return the individual to duty only after identifying and resolving the cause of the impairing condition, and

making a determination of fitness indicating that the individual is fit to safely and competently perform his or her duties (see the discussion of proposed §26.189 [Determination of fitness] for a more detailed discussion of the determination of fitness process). The proposed paragraph would not require licensees and other entities to unfavorably terminate an individual's authorization for illness, fatigue, temporary mental and emotional stress, or other conditions that may affect an individual's fitness, but would prohibit the licensee or other entity from assigning the impaired individual to perform job duties that require the individual to be subject to this part until a determination is made that the individual is fit to return to duty.

Proposed §26.77(c) would update current §26.27(d) to be consistent with current NRC notification procedures.

Subpart E – Collecting Specimens for Testing

Section 26.81 Purpose

Proposed §26.81 [Purpose] would be added to describe the purpose of proposed Subpart E, which would be to establish requirements for collecting specimens for drug and alcohol testing. Adding the proposed section at the beginning of the proposed subpart would assist in locating provisions within the rule and so would be consistent with Goal 6 of the rulemaking, which is to improve clarity in the organization and language of the rule.

Section 26.83 Specimens to be collected

A new §26.83 [Specimens to be collected] would specify the types of specimens that licensees and other entities must collect for initial and confirmatory drug and alcohol testing.

Proposed §26.83(a) would require licensees and other entities to collect either breath or oral fluids (i.e., saliva) for initial tests for alcohol. The proposed rule would continue to require collecting only breath specimens for confirmatory alcohol testing. The proposed rule would add permission to use oral fluids (i.e., saliva) for initial alcohol tests because devices for testing oral fluids for alcohol have matured sufficiently to provide valid and reliable initial test results. Further, there may be circumstances, such as collecting a specimen of oral fluids from a donor who has impaired lung functioning, in which the use of such devices is more efficient for both donors and the FFD program than collecting breath specimens. Therefore, the proposed permission to collect oral fluids for initial alcohol testing would meet Goal 3 of this rulemaking, which is to improve the efficiency of FFD programs. Additionally, other Federally mandated alcohol testing programs permit the use of these devices for initial alcohol testing. Therefore, adding permission to collect oral fluids for initial alcohol testing to the proposed rule would also be consistent with Goal 1 of the rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The proposed rule would eliminate the use of blood as a specimen for alcohol testing at the donor's discretion, which is permitted in current §26.24(g) and Section 2.2(d)(4) in Appendix A to Part 26. The proposed rule would eliminate the current provisions related to blood alcohol testing for several reasons. Since the current rule was first promulgated, licensees have repeatedly raised questions related to the proper interpretation of a confirmatory alcohol test result using an evidential breath testing device (EBT) and an alcohol test result derived from a blood specimen when the results from the two types of testing differ. Specifically, if a confirmatory alcohol test result using an EBT is positive, but the result from testing a blood specimen is negative, licensees have asked which test result they should rely on in determining whether the donor has violated the FFD policy. Although the NRC's original

intent was that the result from the blood test was to be definitive, delays in obtaining a blood specimen have sometimes resulted in blood test results that fell below the alcohol cutoff level of 0.04 percent BAC due to alcohol metabolism during the period of the delay. Some licensees have been reluctant to apply sanctions for a positive alcohol test result in these instances even though alcohol metabolism over time would explain the lower test result from the blood sample. Further, experience has shown that few donors request testing of a blood sample. Data gathered from a sampling of representative FFD programs show that individuals requested an average of fewer than one blood test per program within the period reviewed (January–May 2002). Additionally, the use of EBTs for confirmatory alcohol tests has consistently withstood legal challenge. The added protection of donors' rights that was envisioned when the provisions for voluntary testing of blood specimens were incorporated into the current rule has not been realized in practice. The current requirement has also been costly for licensees, who are required to ensure that an individual who is trained to draw blood is available to do so, should a donor request blood testing. Based upon information provided by stakeholders at the public meetings discussed in Section V, the NRC determined that the costs associated with retaining this provision are not justified because of the very few instances in which donors have requested blood alcohol testing. Therefore, references to collecting and testing blood specimens for alcohol would be deleted from the proposed rule.

Proposed §26.83(b) would retain but make explicit the implied requirement in the first sentence of current §26.24(b) (and other provisions that are interspersed throughout the current rule) for licensees and other entities to collect only urine specimens for drug testing. At the time the current rule was promulgated, it was unnecessary to establish an explicit requirement to collect and test only urine specimens for drugs in Part 26 programs because methods for testing other specimens were not available and the HHS Guidelines only addressed testing

urine specimens. Since that time, methods for testing alternate specimens, such as oral fluids, sweat, and hair, have become commercially available and the HHS has published proposed revisions to its Guidelines (69 FR 19673; April 13, 2004) that would permit the use of such alternate specimens for drug testing in Federal workplace drug testing programs. The NRC is considering permitting the use of alternate specimens for drug testing when the HHS has published final revisions to its Guidelines related to these types of specimens. The revised HHS Guidelines will identify acceptable collection procedures and testing methods. However, HHS has not yet published final Guidelines for collecting and testing these alternate specimens. Therefore, it is necessary to add §26.83(b) to the proposed rule to clarify that the NRC intends to continue prohibiting the collection and drug testing of specimens other than urine in this rulemaking, except as permitted under proposed §26.31(d)(5) [Medical conditions] for the reasons discussed with respect to that paragraph.

Section 26.85 Collector qualifications and responsibilities

A new §26.85 [Collector qualifications and responsibilities] would replace the collector qualifications and training requirements that are specified in the definition of “collection site person” in current Sections 1.2, 2.2(d), and 2.4(b) in Appendix A to Part 26. The intent of the current provisions would be retained in the proposed section, but the proposed rule would group the requirements together within this section for organizational clarity in the rule. In addition, as will be described below, the proposed rule would amend the current collector qualifications and training requirements to increase the consistency of Part 26 with the requirements of other Federal agencies and incorporate the lessons learned from those programs, as discussed in Section IV. B with respect to Goal 1 of this rulemaking.

Proposed §26.85(a) [Urine collector qualifications] would be added to provide more detailed requirements for urine collector qualifications and training than are contained in the current definition of “collection site person” and current Section 2.2(d) in Appendix A to Part 26. The proposed paragraph would require urine collectors to be knowledgeable of the requirements of this part, the FFD policy and procedures of the licensees or other entities for whom collections are performed, and keep current on any changes to urine collection procedures. The proposed changes would increase the consistency of urine collector qualification requirements with those of other Federal workplace drug testing programs as well as consistency between Part 26 urine collection procedures. These more detailed requirements would be added for the reasons discussed in Section IV. C.

Proposed §26.85(a) would retain the requirements in current Section 2.2(d) that urine collectors must receive training to perform their duties and demonstrate proficiency in applying the requirements of the proposed paragraph before serving as a collector. Proposed §26.85(a)(1)–(a)(3) would list the topics that the proposed rule would require collector training to address. Proposed §26.85(a)(1) would require collectors to be trained in the steps that are necessary to complete a collection correctly and the proper completion and transmission of the custody-and-control form to the licensee testing facility or HHS-certified laboratory, as appropriate. Proposed §26.85(a)(2) would require training in methods to address “problem” collections, which may include, but would not be limited to, collections involving “shy bladder” (see the discussion of proposed §26.119 [Determining “shy” bladder] for an explanation of this term and the procedures involved) and attempts by a donor to tamper with a specimen. Proposed §26.85(a)(3) would require the training to instruct collectors on how to correct problems in collections, which may include, but would not be limited to, a donor refusing to cooperate with the collection process or an incident in which a urine specimen is spilled. These

proposed requirements would be added to meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.85(a)(4) would retain the portion of current Section 2.2(d)(1) in Appendix A to Part 26 that requires collector training to emphasize the collector's responsibility for maintaining the integrity of the specimen collection and transfer process, to carefully ensure the modesty and privacy of the donor, and avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

Proposed §26.85(b) [Alcohol collector qualifications] would be added to specify requirements related to alcohol collector qualifications and training. Portions of this paragraph would be the same as the requirements for urine collectors in proposed §26.85(a), including the first three sentences of proposed §26.85(b) and proposed §26.85(b)(4) and (b)(5), and would be added here for the same reasons discussed above with respect to the first three sentences of proposed §26.85(a), and proposed §26.85(a)(3) and (a)(4), respectively. The proposed rule would repeat the requirements that are applicable to both urine and alcohol collectors in each of these paragraphs because some FFD programs may not train collectors to perform both types of collections. Repeating the requirements would make it easier to locate the requirements that apply to urine or alcohol collectors, respectively, to meet Goal 6 of the rulemaking, which is to improve clarity in the organization of the rule.

Proposed §26.85(b)(1) and (b)(3) would require alcohol collectors to receive training that addresses the alcohol testing requirements of this part and methods to address "problem" collections, including, but not limited to, collections involving "shy lung" problems or attempts by a donor to tamper with a specimen. By contrast to proposed §26.85(a)(2), which addresses "shy bladder" problems in urine collections, the proposed rule would not incorporate the related

DOT procedures for determining “shy lung” problems in alcohol collections. During the public meetings discussed in Section V, stakeholders requested that the proposed rule incorporate DOT’s “shy bladder” procedures, but did not believe that adding DOT’s “shy lung” procedures to the proposed rule is necessary. The stakeholders reported that “shy lung” has not been a problem for donors, based on their experience implementing the breath testing requirements of Part 26 since the rule was first promulgated. Therefore, proposed paragraph §26.85(b)(3) would require alcohol collectors to be able to implement the “shy lung” procedures established by any FFD program for whom the collectors are providing collection services, but would not establish requirements for responding to “shy lung” problems in the rule. The NRC invites comment on this omission.

Proposed §26.85(b)(2) would be added to require alcohol collectors to be trained in the operation of the particular alcohol testing device(s) [i.e., the alcohol screening devices (ASDs) and evidential breath testing devices (EBTs)] to be used in conducting alcohol tests, consistent with the most recent version of the manufacturers’ instructions. The proposed rule would add a requirement for alcohol collectors to be trained to follow the most recent version of the testing device manufacturers’ instructions because the NRC is aware that some FFD programs did not implement device manufacturers’ recommended changes to instructions for using the testing devices. Although the NRC staff is not aware of any testing errors or instances in which donors have challenged the results of alcohol tests that were not performed in accordance with the most recent version of the device manufacturer’s instructions, the proposed rule would add this requirement to ensure that alcohol test results continue to be accurate and cannot be challenged on this basis. The proposed changes would also be consistent with the alcohol collector training requirements of other Federal agencies.

Proposed §26.85(c) [Alternative collectors] would amend the last sentence of current Section 2.2(d)(2) in Appendix A to Part 26, which permits medical personnel to perform specimen collections without receiving the training that is required for non-medical collectors. The proposed rule would permit medical personnel to conduct specimen collections for the purposes of this part only under the conditions that would be specified in proposed §26.85(c)(1)–(c)(5), which may include, but would not be limited to the collection of specimens for post-event testing by a nurse or medical technician at a hospital. The proposed rule would limit the circumstances in which an untrained medical professional, technologist, or technician may perform collections for a licensee or other entity because the experience of other Federal agencies has shown that medical personnel who are untrained in specific collection procedures have committed errors in collections that resulted in unnecessary legal challenges to test results. At the same time, the NRC is also aware that licensees and other entities may occasionally have to rely upon such individuals to collect specimens for drug and alcohol testing, as discussed with respect to proposed §26.25(b)(1). Therefore, the proposed rule would permit untrained medical personnel to collect specimens to facilitate the collection of specimens for testing in rare circumstances in which a qualified collector could not reasonably be expected to be available, but would otherwise require medical personnel who do not meet the criteria specified in proposed §26.85(c)(1)–(c)(5) to receive the same training as non-medical collectors. The proposed change would be made to meet Goal 3 of the rulemaking, which is to improve the effectiveness and efficiency of FFD programs, by reducing the likelihood of errors and legal challenges to test results.

The proposed rule would eliminate current Section 2.2(d)(4) in Appendix A to Part 26, which requires that donors must be informed of the option to request blood testing. The current

requirement would be eliminated because blood specimens would no longer be used for alcohol testing, as discussed with respect to current §26.83(a).

Proposed §26.85(d) would amend current Section 2.7(o)(5) [Personnel available to testify at proceedings] in Appendix A to Part 26, which requires that the licensee testing facility and HHS-certified laboratory must make available qualified individuals to testify in administrative or disciplinary proceedings related to drug and alcohol test results. The proposed rule would add an explicit requirement for collection site personnel to be available to testify at proceedings because this requirement is implied but not explicitly stated in the current provision. At the time the rule was first published, licensee testing facilities and collection sites were typically co-located at a site. However, this is no longer the case. In some current FFD programs, alcohol testing and urine specimen collections occur at the collection site, but initial testing of urine specimens is performed at a licensee testing facility, which may not be co-located with the collection site. Therefore, the proposed rule would add this paragraph to retain the NRC's original intent that licensees and other entities must make available collection site personnel to testify, as needed, in administrative and/or legal proceedings related to an alcohol or drug test result. For organizational clarity, the requirements in the current paragraph that address the availability of personnel to testify in proceedings related to drug test results from the licensee testing facility would be moved to §26.139(c) of proposed Subpart F [Licensee Testing Facilities] and those related to HHS-certified laboratories would be moved to §26.153(f)(2) of proposed Subpart G [Laboratories Certified by the Department of Health and Human Services].

26.87 Collection sites

A new §26.87 [Collection sites] would be added to reorganize current requirements related to specimen collection sites. In general, the proposed rule would group together in this section the requirements that are related to collection sites, which are currently distributed among several different sections in Appendix A to Part 26. The proposed change would be made to meet Goal 6 of this rulemaking, which is to improve organizational clarity in the rule.

Proposed §26.87(a) would amend current Section 2.4(a) in Appendix A to Part 26, which requires FFD programs to designate collection sites and ensure that they are fully equipped to collect specimens for testing. The proposed paragraph would delete reference to blood specimens because the proposed rule would no longer provide donors with the option to request blood testing for alcohol for the reasons discussed with respect to proposed §26.83(a). The proposed paragraph would add a requirement for collection sites to be capable of alcohol testing, which was implied in the current paragraph but not explicitly stated. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule. The proposed paragraph would retain the current permission for licensees and other entities to use properly equipped mobile collection facilities.

Proposed §26.87(b) would revise the first sentence of current Section 2.4(f) in Appendix A to Part 26 to require visual privacy for donors while the donor and collector are viewing the results of an alcohol test and retain the current requirement for individual privacy during urine specimen collections, except if the urine specimen collection must be conducted under direct observation. The new requirement for visual privacy while viewing alcohol test results would increase the consistency of Part 26 with the alcohol testing procedures of other Federal agencies and assure greater privacy for donors who are subject to FFD programs who do not provide visual privacy under the current rule. This proposed change would be made to

meet Goal 7 of this rulemaking, which is to protect the privacy of individuals who are subject to Part 26. For organizational clarity, the proposed rule would move the current requirements in Section 2.4(f) in Appendix A to Part 26 that are related to collecting a specimen under direction observation to proposed §26.115 [Collecting a urine specimen under direct observation].

Proposed §26.87(c) would retain only the portion of current Section 2.7(m) in Appendix A to Part 26 that requires licensees' and other entities' contracts for collection site services to permit unfettered NRC, licensee, and other entity access to collection sites for unannounced inspections. For organizational clarity, the requirements in the current paragraph related to licensee testing facilities would be relocated to proposed Subpart K [Inspections, Violations, and Penalties] and subsumed under proposed §26.221(a). The portions of the current paragraph that apply to HHS-certified laboratories would be moved to §26.153(f) of proposed Subpart G [Laboratories Certified by the Department of Health and Human Services], also for organizational clarity. In addition, proposed §26.87(c) would add a requirement that licensees' and other entities' contracts for collection site services must permit unfettered NRC, licensee, and other entity access to all information and documentation that is reasonably relevant to inspections and audits. This proposed requirement for access to documentation would be added for consistency with the HHS Guidelines, which also require collection sites to provide information and documentation as part of inspections and audits. Therefore, this proposed change would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. The term, "audit," would be added to the proposed paragraph because, although the NRC conducts inspections, licensees and other entities would be required to conduct audits under proposed §26.41 [Audits and corrective action]. Adding this term to the proposed paragraph would increase the clarity of its language, consistent with Goal 6 of the rulemaking.

Proposed §26.87(d) would revise current Section 2.4(c) in Appendix A to Part 26 to clarify current requirements for assuring collection site security and the integrity of specimen collection procedures. The proposed rule would group requirements related to assuring the security of a licensee's or other entity's designated collection site in this proposed paragraph for organizational clarity. The requirements contained in current Section 2.4(c) in Appendix A to Part 26 that address assuring collection security when a designated collection site is inaccessible and there is an immediate requirement to collect a urine specimen would be moved to proposed §26.87(f), also for organizational clarity. The proposed paragraph would include other clarifying changes to current Section 2.4(c) in Appendix A to Part 26, in response to stakeholder requests for such clarifications at the public meetings discussed in Section V, as follows:

Proposed §26.87(d)(1) would retain the first sentence of current Section 2.4(e) in Appendix A to Part 26, which requires that only authorized personnel may have access to any part of a collection site in which specimens are collected and stored. This requirement would be moved to the proposed paragraph because it addresses the topic of collection site security. Therefore, this change would be made for organizational clarity.

Proposed §26.87(d)(2) would amend the second sentence of current Section 2.4(c) in Appendix A to Part 26, which requires collection sites to be secure, by providing examples of acceptable methods to assure collection site security. The proposed rule would add these examples in response to stakeholder requests during the public meetings discussed in Section V. The stakeholders noted that the requirement that collection sites "must be secure" has raised many implementation questions. Therefore, the proposed rule would add examples of acceptable means to ensure collection site security, including, but not limited to, physical measures to control access, such as locked doors, alarms, or visual monitoring of the collection

site when it is not occupied. The proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

Proposed §26.87(d)(3) would amend the third sentence in current Section 2.4(c) in Appendix A to Part 26, which requires that the portion of any facility that is not dedicated solely to drug and alcohol testing must be secured during testing, and combine it with the third sentence of current Section 2.4(c)(1) in Appendix A to Part 26, which requires posting the facility against unauthorized access during the collection. The proposed rule would replace the phrase, "in the case of a public restroom," in the last sentence of current Section 2.4(c)(1) in Appendix A to Part 26, with the phrase, "if a collection site cannot be dedicated solely to collecting specimens," to clarify that a specimen may be collected at locations other than public restrooms. The proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.87(e) would be added to specify the steps that licensees and other entities must take to deter dilution and adulteration of specimens during urine collections. The proposed paragraph would retain and amend portions of current Section 2.4(g) in Appendix A to Part 26, as explained below:

Proposed §26.87(e)(1) would relax the requirement for use of a bluing agent in any source of standing water, such as a toilet bowl or tank, in current Section 2.4(g)(1) of Appendix A to Part 26. The proposed rule would permit licensees and other entities to use colors other than blue. A yellow coloring agent would not be permitted because it would preclude the collector's ability to determine whether a donor had diluted the specimen with water from a source of standing water in the stall or room in which the donor provides a specimen. The proposed relaxation would not affect the accuracy of drug tests, but would give FFD programs increased flexibility in the choice of coloring agents. The proposed rule would

make this change in response to stakeholder requests during the public meetings discussed in Section V and to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Proposed §26.87(e)(1) would also add a requirement that the coloring agents that are added to any source of standing water in the stall or room in which the donor is to provide a specimen cannot interfere with drug or validity tests. The proposed requirement would be necessary to ensure that, if a donor attempted to subvert the testing process through diluting his or her specimen, the coloring agent would not interfere with testing assays and, therefore, would permit the detection of prohibited drug use. The proposed requirement would meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs, by deterring dilution attempts using sources of standing water and increasing the likelihood that dilution attempts of this type would be detected.

Proposed §26.87(e)(2) would retain the second sentence of current Section 2.4(g)(1) in Appendix A to Part 26, which requires sources of standing water to be secured, but shorten it without changing the intended meaning of the requirement. The proposed change would be made to improve clarity in the language of the rule.

Proposed §26.87(e)(3) would be added to require that chemicals or products that could be used to adulterate a urine specimen must be secured or removed from the collection site. The collector would also be required to inspect the enclosure to ensure that no potential adulterants are available before the donor would enter the stall or enclosure. These requirements would be added to prevent possible donor attempts to subvert the testing process by adulterating a urine specimen with materials that are available at the collection site. The proposed rule would add this provision to meet Goal 3 of this rulemaking, which is to improve

the effectiveness of FFD programs. The proposed provision would also be consistent with the related requirements of other Federal agencies.

Proposed §26.87(f) would reorganize current Section 2.4(c)(1), portions of Section 2.4(c)(2), and Section 2.4(g)(10) in Appendix A to Part 26 to prescribe acceptable procedures for collecting specimens at locations other than a designated collection site in unusual circumstances, such as a specimen collection for post-event testing at a hospital. The proposed rule would group these requirements together in a single paragraph and separate them from those related to collecting specimens at a designated collection site in proposed §26.87(d) and (e) to make it easier to locate these requirements within the rule. The proposed change would be made to improve organizational clarity in the rule.

Proposed §26.87(f)(1) would amend current Section 2.4(c)(1) in Appendix A to Part 26, which establishes requirements for securing a location that is not a designated collection site but will be used for a specimen collection(s). The proposed rule would require either an individual to guard access to a public rest room while the collection is occurring, or the posting of a sign to ensure that no unauthorized personnel enter the area during the collection. The current rule requires only the posting of a sign, but stationing an individual to guard access would be at least as effective. The proposed rule would permit an individual to guard access to the collection area in response to stakeholder requests for this flexibility during the public meetings discussed in Section V. The proposed change would be made to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Proposed §26.87(f)(2) would retain the third sentence of current Section 2.4(g)(10) in Appendix A to Part 26 that requires a water-coloring agent to be used, if possible, to deter a possible dilution or adulteration attempt when a collection must occur at a location other than the licensee's or other entity's designated collection site.

Proposed §26.87(f)(3) would amend the second sentence of current Section 2.4(g)(10), which requires that the collector must be the same gender as the donor. If a collector of the same gender is unavailable, the proposed paragraph would permit another person of the same gender who is instructed in the requirements of proposed Subpart E [Collecting specimens for testing] to assist in the collection. The proposed paragraph would require either the collector or the observer to remain outside the area in which the donor will provide the urine specimen to protect the donor's privacy and the integrity of the collection process. The proposed rule would require the observer's identity to be documented on the custody-and-control form so that the observer may be located should any subsequent questions arise with respect to the collection in a review under proposed §26.39 [Review process for fitness-for-duty policy violations] or legal proceedings. The flexibility to rely on a person of the same gender as an observer, if a collector of the same gender is unavailable, would be consistent with the procedures of other Federal agencies and reduce potential embarrassment to the donor. Therefore, this proposed change would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, and Goal 7, which is to protect the privacy of individuals who are subject to Part 26.

Proposed §26.87(f)(4) would require the collector, once he or she is in possession of the donor's specimen, to inspect the area in which the specimen donation occurred for any evidence of a subversion attempt by the donor. The proposed paragraph would amend the fifth and sixth sentences of current Section 2.4(g)(10) in Appendix A to Part 26 that describe the required sequence of actions during a specimen collection and specify that a donor is permitted to flush the toilet after a specimen donation. The proposed rule would eliminate the option for the donor to flush the toilet and would direct the collector to instruct the donor not to flush the toilet. The proposed change would reduce the possibility that a donor could dispose of

evidence of a subversion attempt by flushing it down the toilet. Proposed §26.87(f)(4) would direct the collector to inspect the toilet bowl and area once he or she receives the specimen from the donor. The proposed rule would add these provisions to reduce the opportunities for a donor to subvert the testing process and to meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs. The proposed requirement would also meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.87(f)(5) would amend the portions of current Section 2.4(c)(2) in Appendix A to Part 26 that define requirements for maintaining control of specimens that are not collected at a designated collection site. An "authorized individual," including, for example, a security officer or hospital medical technician, would be permitted to maintain physical custody and control of specimens in the proposed paragraph, rather than only the collector, as is required in the current rule. The "authorized individual" would be designated by the licensee or other entity and instructed in his or her responsibilities for maintaining custody and control of the specimen. The authorized individual's custody of the specimen would be documented on the custody-and-control form to ensure that the individual may be located should any subsequent questions arise with respect to the collection in a review under proposed §26.39 [Review process for fitness-for-duty policy violations] or legal proceedings. The proposed change would continue to ensure specimen integrity and security, but would respond to industry experience, as described by stakeholders at the public meetings discussed in Section V. The stakeholders reported that it is sometimes difficult in unusual circumstances, such as the hospital setting, for the collector to maintain physical custody of the specimen until it is prepared for transfer, storage, or shipping. Therefore, the proposed change would be made to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary

requirements, while continuing to protect the privacy and due process rights of individuals who are subject to Part 26.

Section 26.89 Preparing to collect specimens for testing

A new §26.89 [Preparing to collect specimens for testing] would describe the preliminary steps to be taken by the collector and donor before specimens are collected for drug and alcohol testing. The proposed section would reorganize and amend portions of the current Appendix A to Part 26, and add several new requirements, as explained below. The proposed rule would present these requirements in a new section to facilitate locating them within the proposed rule to meet Goal 6 of this rulemaking, which is to improve clarity in the organization of the rule.

Proposed §26.89(a) would provide more detailed requirements than those contained in current Section 2.4(g)(3) in Appendix A to Part 26 for actions to be taken if an individual does not appear for testing. The current rule requires the collector to contact an "appropriate authority" to determine the actions to take if a donor does not appear for testing. At the public meetings discussed in Section V, some stakeholders indicated that the lack of specificity in the current rule with respect to the actions that the "appropriate authority" must take in these circumstances has led some FFD programs to interpret this provision as requiring the imposition of the sanctions for a "refusal to test" on an individual who fails to appear, including situations in which there is clear evidence that the individual had not been informed that he or she was required to appear for testing or was otherwise not at fault for the failure. This is not the intent of the current provision. Therefore, under the proposed paragraph, when informed that an individual who was selected for testing has not appeared at the required time, FFD program management would be required to ensure that the circumstances are investigated and

determine whether the individual's absence or tardiness represents an attempt to avoid testing and, therefore, subvert the testing process. The proposed rule would require the licensee or other entity to impose the sanctions specified in proposed §26.75(b) for a refusal to test only if the investigation identifies evidence that the individual's failure to appear for testing was a subversion attempt. If evidence of a subversion attempt is not identified, the proposed rule would prohibit the licensee or other entity from imposing sanctions and require the individual to be tested at the earliest reasonable and practical opportunity after the individual is located. These more detailed requirements would be added to strengthen the rule's effectiveness in preventing subversion by ensuring that a failure to appear for testing is investigated, which would increase the likelihood of detecting a willful attempt to avoid testing. In addition, the proposed requirements would prevent an individual from being subject to a permanent denial of authorization, as would be required under proposed §26.75(b), if the individual's failure to appear is determined to be outside of the individual's control or otherwise not a result of a willful attempt to avoid testing. These proposed changes would be made to meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs, and Goal 7, which is to protect the due process rights of individuals who are subject to Part 26.

Proposed §26.89(b) would reorganize and expand current Section 2.4(g)(2) in Appendix A to Part 26, which requires the collector to ensure that an individual who arrives at the collection site for testing is positively identified. The proposed rule would add more detailed requirements for the reasons discussed with respect to each requirement in the proposed paragraph.

Proposed §26.89(b)(1) would specify the types of photo identification that the licensee or other entity may accept to identify the donor. Identification of the donor by the employer's representative would no longer be permitted. The NRC is not aware of any incidents in which

an employer's representative has inaccurately identified an individual who appeared for testing without acceptable identification. However, permitting collectors to rely on identification by an employer's representative provides an opportunity for individuals to conspire to subvert the testing process by substituting the designated donor, who may have engaged in substance abuse, with another individual who has not abused illegal drugs or alcohol. Such a conspiracy could prevent an individual's substance abuse from being detected through testing. Therefore, this proposed revision would be made to provide greater assurance that the individual who appears for testing is the designated donor and, thereby, strengthen the effectiveness of FFD programs in detecting substance abuse. The proposed change would also increase the consistency of Part 26 with access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003, which is Goal 4 of this rulemaking.

Proposed §26.89(b)(2) would amend the portion of current Section 2.4(g)(2) in Appendix A to Part 26 that directs the collector to stop the collection if the individual cannot be positively identified. By contrast, the proposed paragraph would direct the collector to proceed with the collection and inform FFD program management that the donor did not present acceptable photo identification. The proposed paragraph would require FFD management to take the necessary steps to determine whether the lack of identification is an attempt to subvert the testing process. However, the proposed paragraph would retain the current requirement for the collector to delay the collection until the individual can be identified if it a pre-access test. The proposed changes would be made for several reasons:

First, lessons learned from implementing the current rule have indicated that the large majority of failures to present acceptable identification are the result of miscommunication or other errors that are easily resolved. However, stopping or delaying the specimen collection

may alter test results (e.g., if an individual has consumed alcohol, the individual's alcohol test result would show a lower BAC after a delay or may not be detected if testing is not conducted). Therefore, collecting the specimens first and then resolving the individual's identity would assure that test results would be available and accurate from donors who are currently authorized and whose identity has previously been confirmed by the licensee or other entity. Therefore, this proposed change would meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

Second, the current requirement to stop the collection without investigating the reasons that the individual is unable to present acceptable identification does not ensure that an attempt by an individual to subvert the testing process is detected. For example, an individual who has engaged in substance abuse could delay specimen collection by claiming to have "forgotten" his or her photo identification in his or her car or locker. Permitting the individual to leave the collection site to obtain his or her identification would provide an opportunity for the individual to obtain an adulterant or substitute urine that he or she could then use to subvert the testing process. Steps that FFD program management could take to investigate the reasons that the individual did not present acceptable identification in this instance could include assigning a security officer to accompany the individual to his or her car or locker to verify the individual's claim, as well as to ensure that the individual does not have the opportunity to bring an adulterant or substitute urine back to the collection site. Therefore, the proposed requirement would strengthen the effectiveness of FFD programs in detecting attempts to subvert the testing process.

The requirement to delay the collection until the individual presents acceptable identification if it is a pre-access test would be retained from the current rule at the request of stakeholders during the public meetings discussed in Section V. The stakeholders noted that

the current requirement to delay pre-access testing until the individual presents acceptable photo identification does not present a risk to public health and safety or the common defense and security from a possible subversion attempt because the individual would not yet have access to sensitive information, radiological materials, or safety systems and equipment. Further, stakeholders noted that retaining the current provision would save them the expense associated with collecting and testing a specimen that may be collected from the wrong individual. The NRC concurs that it is reasonable to retain the current requirement as it relates to pre-access tests for the reasons given by the stakeholders.

Proposed §26.89(b)(3) would update current Sections 2.4(g)(4) and 2.4(g)(23)(ii) in Appendix A to Part 26, in which, before any specimens are collected, donors are required to list the prescription and over-the-counter medications they have used within the 30 days before testing. To be consistent with the privacy requirements of the Americans with Disabilities Act [Pub. L. 101-336, July 26, 1990], the proposed rule would eliminate the requirement to list medications prior to specimen collection and testing. The proposed rule would require donors to provide medication information to the MRO only in the event of non-negative confirmatory validity or drug test results in order to enhance their rights to privacy under the rule. This revised requirement would also be consistent with the procedures of other Federal agencies and would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.89(b)(3) would also add a requirement for the collector to explain the testing procedure to the donor. Current Section 2.2(d)(3) in Appendix A to Part 26 requires that individuals who are subject to testing must be provided with standard written instructions setting forth their responsibilities. However, the NRC is aware that these instructions are typically provided to individuals as part of the training that is required under current §26.21 [Policy

communications and awareness training] rather than at the collection site before starting the specimen collection process, which was not the intent of Section 2.2(d)(3) in Appendix A to Part 26. Rather than retaining and clarifying the current provision for standard written instructions, which some individuals have may difficulty comprehending, the proposed rule would adopt the related practices of other Federal agencies, which require the collector to explain the testing procedure to the donor. This proposed change would ensure that individuals are informed of the testing process in which they must participate and their responsibilities within it to meet Goal 7 of this rulemaking, which is to protect the due process rights of individuals who are subject to Part 26. In addition, the proposed revision would enhance the consistency of Part 26 with the requirements of other Federal agencies.

Proposed §26.89(c) would be added to ensure that the donor is aware of his or her responsibilities to cooperate with the specimen collection process. The proposed paragraph would respond to reports from stakeholders at the public meetings discussed in Section V that some donors have attempted to obstruct or delay the collection process on the basis that the donor's responsibility to cooperate with the collection process is implied, but not clearly specified, in the current rule. Therefore, the proposed paragraph would eliminate that basis for obstructing or delaying collections, which would improve the effectiveness and efficiency of FFD programs, consistent with Goal 3 of this rulemaking.

The proposed paragraph would also require the collector to inform the donor that a failure to cooperate in the specimen collection process would be considered a refusal to test and may result in the permanent denial of authorization under proposed §26.75(b). Informing donors of the potential consequences of failing to cooperate in the collection process, in advance, would be consistent with Goal 7 of this rulemaking, which is to protect the due

process rights of individuals who are subject to Part 26. The requirements of this proposed paragraph would also be consistent with the practices of other Federal agencies.

Proposed §26.89(d) would retain the last two sentences of current Section 2.4(e) in Appendix A to Part 26. These sentences require the collector to conduct only one urine specimen collection at a time and define the point at which the collection process ends, which is when the donor has left the collection site. The proposed paragraph would be retained in this section because it relates to the topic of the proposed section, which is preparing for specimen collections, to ensure that collectors are aware of this requirement before they begin collecting any specimens. The proposed change would improve the organizational clarity of the rule.

Section 26.91 Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use

A new §26.91 [Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use] would amend current requirements for alcohol testing devices and methods of use. The requirements in the current rule that are related to this topic appear in current §26.24(g) and Sections 2.4(g)(18) and 2.7(o)(3)(ii) in Appendix A to Part 26. The proposed section would combine these requirements into one section, amend the current requirements, and add others, as explained below. The proposed rule would group these requirements in one section to meet Goal 6 of this rulemaking, which is to improve clarity in the organization of the rule.

Proposed §26.91(a) [Acceptable alcohol screening devices] would be added to permit the use of alcohol screening devices (ASDs) for initial testing and establish requirements for the ASDs that may be used. Acceptable ASDs would include alcohol saliva analysis devices and

breath testing devices that are listed on the most recent version of NHTSA's Conforming Products List (CPL) for ASDs (May 4, 2001, 66 FR 22639, and subsequent amendments thereto). Current Section 2.7(o)(3)(ii) in Appendix A to Part 26 limits FFD programs to using only evidential-grade breath testing devices. However, permitting FFD programs to use ASDs listed on NHTSA's CPL for initial alcohol testing would be consistent with other Federal agencies' procedures for workplace alcohol testing. Therefore, the proposed change would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Further, permitting the use of some ASDs for initial alcohol testing would provide increased flexibility in conducting initial alcohol tests. Licensees and other entities may find that, over time, it is less expensive to use a particular ASD than to continue using EBTs for all initial alcohol tests. The option to use alcohol saliva analysis devices also may reduce the burden of alcohol testing for some donors, such as individuals who have impaired lung functioning. The proposed rule's permission to use ASDs that are listed on NHTSA's CPL for ASDs for initial alcohol testing would meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements, by increasing FFD programs' flexibility in administering initial alcohol tests.

A new §26.91(b) [Acceptable evidential breath testing devices] would amend current Section 2.7(o)(3)(ii) in Appendix A to Part 26 and establish new requirements for the EBTs that licensees and other entities must use for confirmatory alcohol breath testing. The proposed paragraph would require licensees and other entities to use EBTs that are listed on the most recent version of NHTSA's CPL for evidential breath testing devices (October 3, 2002, 67 FR 62091, and subsequent amendments thereto) when conducting confirmatory alcohol tests, and permit licensees and other entities to use these EBTs for conducting initial alcohol

tests. These EBTs incorporate many improvements in EBT technology and have been shown to accurately detect BACs at the 0.02 percent level. Therefore, they are the appropriate instruments to use for testing at the revised alcohol cutoff levels specified in proposed §26.103 [Determining a confirmed positive test result for alcohol].

Further, because these EBTs have been shown to provide valid, reliable, and legally defensible results in other Federal programs that also require workplace alcohol testing, the proposed requirement to use these EBTs would permit two additional proposed changes to the alcohol testing procedures contained in current Section 2.4(g)(18) in Appendix A to Part 26: (1) collecting only one breath specimen for the initial alcohol test and one for the confirmatory test in proposed §§26.95(c) and 26.101(c), rather than the two specimens that are currently required for each test; and (2) conducting both the initial and confirmatory tests (if a confirmatory test is required) using the same EBT in proposed §26.101(d). As discussed further with respect to proposed §§26.95(c) and 26.101(c) and (d), these proposed changes to the current alcohol testing requirements would improve the efficiency of alcohol testing while continuing to provide valid, reliable, and legally defensible results that are necessary to protect donor's rights under workplace alcohol testing programs. The use of these improved EBTs is similarly required for confirmatory alcohol testing and permitted for initial testing under 49 CFR Part 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs" (65 FR 41944; August 9, 2001). Therefore, this proposed change would also meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines; Goal 3, which is to improve the efficiency of FFD programs; and Goal 5, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Proposed §26.91(c) [EBT capabilities] would be added to specify the required capabilities of the EBTs that licensees and other entities may use for initial alcohol testing and must use for confirmatory alcohol tests. The EBT capabilities listed in proposed §26.91(c)(1)–(c)(3) are necessary to ensure that a test result can be uniquely associated with the instrument used, the time of testing, and the donor. These capabilities are necessary in order to establish an unimpeachable chain of custody for alcohol test results as well as permit the accurate identification of any test results that may have been affected by instrument malfunctions that are discovered later through additional quality assurance checks. The EBT capabilities listed in proposed §26.91(c)(4)–(c)(6) would ensure that test results will be accurate by permitting collectors to verify that the instrument is functioning properly before each test and there will be no carryover effects from previous testing. These capabilities would improve the effectiveness and efficiency of confirmatory alcohol testing by limiting the need to cancel test results due to instrument errors, as required under proposed §26.91(e)(3). Using EBTs that have the required capabilities for confirmatory alcohol tests would protect donors' rights to accurate test results, provide greater assurance that test results will withstand any legal challenges, and improve an FFD programs' ability to identify tests that may have been affected by instrument errors. Therefore, the proposed requirements would meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

Proposed §26.91(d) [Quality assurance and quality control of ASDs] would be added to establish quality assurance and quality control requirements for ASDs. These proposed requirements are necessary to ensure that initial tests that are conducted using an ASD do not yield false negative test results. If an ASD provides a false negative test result, a donor who has a BAC that exceeds the cutoff levels established in this part would not be detected by the test and may be permitted to perform the job duties that require him or her to be subject to this

part, thereby creating an unacceptable risk to public health and safety or the common defense and security. The proposed (and current) rule would require confirmatory testing if initial alcohol test results are positive, so false positive test results from an ASD would lead to confirmatory testing, which would provide accurate test results. False positive test results reduce the efficiency of FFD programs and inconvenience donors by causing them to be subject to unnecessary confirmatory testing, but do not pose any risks to public health and safety or the common defense and security. However, confirmatory testing is not required if the result of an initial alcohol test result is negative. Therefore, the quality assurance and quality control requirements contained in this proposed paragraph would be necessary to maintain the effectiveness of FFD programs, which is Goal 3 of this rulemaking.

Proposed §26.91(d)(1) would be added to require FFD programs to implement the most recent version of the quality assurance plan that a manufacturer has submitted to NHTSA for any ASD that the licensee or other entity uses for initial alcohol testing. In order to obtain NHTSA approval for an ASD, the manufacturer of the device must submit a quality assurance plan that (1) specifies the methods that must be used for quality control checks, (2) the temperatures at which the ASD must be stored and used, (3) the shelf life of the device, (4) environmental conditions (e.g., temperature, altitude, humidity) that may affect the ASD's performance, (5) instructions for its use and care, (6) the time period after specimen collection within which the device must be read, where applicable, and (7) the manner in which the reading is made. The proposed paragraph would require licensees and other entities who intend to use an ASD to obtain and implement the most recent version of the manufacturer's quality assurance plan to ensure that the ASD will not provide false negative test results from improper storage or use. As discussed with respect to proposed §26.91(d), the proposed

provision would be necessary to maintain the effectiveness of FFD programs that rely on ASDs for initial alcohol testing.

Proposed §26.91(d)(2) would be added to prohibit licensees and other entities from using an ASD that fails the quality control checks that would be specified in the most recent version of the manufacturer's quality assurance plan or that has passed its expiration date. This proposed prohibition would be necessary to ensure that test results from using the ASD are accurate both to protect public health and safety and donors' rights to accurate test results under the rule.

Proposed §26.91(d)(3) would be added to require licensees and other entities to follow the device use and care requirements that would be specified in proposed paragraph (e) of this section for an ASD that tests breath specimens. The proposed requirement would be added because some ASDs test specimens of oral fluids while others test breath specimens, and some ASDs that test breath specimens also appear on NHTSA's CPL for evidential breath testing devices (October 3, 2002, 67 FR 62091, and subsequent amendments thereto). Those ASDs that do test breath specimens and would be used for confirmatory testing have more detailed quality assurance and quality control provisions because their results must be legally defensible.

Proposed §26.91(e) [Quality assurance and quality control of EBTs] would establish new quality assurance and quality control requirements for EBTs. The proposed requirements would be consistent with those of other Federal agencies that require workplace alcohol testing and, therefore, would update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, as follows:

Proposed §26.91(e)(1) would add a requirement that licensees and other entities must implement the most recent version of the manufacturer's instructions for the use and care of the

EBT consistent with the quality assurance plan submitted to NHTSA for the EBT, including the frequency of external calibration checks. An EBT manufacturer is required to submit to NHTSA a quality assurance plan that addresses methods used to perform external calibration checks on the EBT, the tolerances within which the EBT is regarded as being in proper calibration, and the intervals at which these checks must be performed. The proposed rule would require licensees and other entities to perform external calibration checks at the manufacturer's recommended intervals, at a minimum. These calibration intervals take into account factors such as frequency of use, environmental conditions (e.g., temperature, humidity, altitude), and type of operation (e.g., stationary or mobile). Therefore, this proposed provision would ensure that the EBT will not provide false test results from improper storage or use.

Proposed §26.91(e)(2) would add a requirement for licensees and other entities to use only calibration devices appearing on NHTSA's CPL for "Calibrating Units for Breath Alcohol Tests" when conducting external calibration checks. This proposed requirement is necessary to ensure that the calibrating units used by licensees and other entities meet minimum standards and provide accurate results.

Proposed §26.91(e)(3) would be added to address circumstances in which an EBT fails an external calibration check. The proposed paragraph would require the licensee or other entity to cancel any positive test results from tests that were conducted during the period since the EBT last passed an external calibration check. This proposed requirement would protect donors' right to due process under the rule because positive test results from an EBT that has failed an external calibration check are questionable and donors should not be subject to sanctions on the basis of these test results. Because most EBT manufacturers' recommended intervals are one month, licensees and other entities may choose to conduct the calibration checks more frequently in order to avoid the proposed test cancellations, should an EBT fail an

external calibration check. The proposed paragraph would also require the licensee or other entity to take the EBT out of service. An EBT that has failed an external calibration check must be taken out of service to avoid inaccurate reporting of breath alcohol test results that could result either in the imposition of sanctions on a donor who has not abused alcohol or the failure to identify a donor who has.

Proposed §26.91(e)(4) would be added to require that inspection, maintenance, and calibration of the EBT must be performed by its manufacturer or a maintenance representative who is certified by the manufacturer, a State health agency, or other appropriate State agency. This proposed provision would ensure that inspection, maintenance, and calibration of EBTs are performed by qualified personnel for two reasons: (1) to ensure that EBTs used in Part 26 programs continue to provide accurate test results, and (2) because the experience of other Federal agencies who require workplace alcohol testing has demonstrated that such stringent EBT inspection, maintenance, and calibration requirements are necessary to withstand legal challenges to alcohol test results.

Section 26.93 Preparing for alcohol testing

A new §26.93 [Preparing for alcohol testing] would expand on current Section 2.4(g)(18) in Appendix A to Part 26, which specifies procedures for alcohol testing. The proposed rule would provide more detailed procedures than the current paragraph to increase the consistency of these procedures with those of other Federal workplace alcohol testing programs as well as consistency among the alcohol testing procedures of Part 26 programs. These more detailed requirements would be added for the reasons discussed in Section IV. B.

Proposed §26.93(a) would contain more detailed procedures for implementing the current requirement in the first sentence of current Section 2.4(g)(18) in Appendix A, which instructs collectors to delay alcohol breath testing for 15 minutes if the donor has engaged in any of the activities listed (e.g., smoking, regurgitation of stomach contents from vomiting). Proposed §26.93(a)(1)–(a)(6) would require the collector to provide the donor with more detailed information about mouth alcohol and the testing process than is currently required and document that the information is provided. Providing more detailed requirements for the 15-minute waiting period would improve the effectiveness and efficiency of the alcohol testing process by reducing false positive test results that are due to residual mouth alcohol or other substances that could potentially trigger a false positive result. Proposed §26.93(a)(1) would retain the current requirement for the collector to ask the donor about behaviors such as eating and drinking that have may have occurred within the 15 minutes before an alcohol test and add a requirement for the collector to advise the donor to avoid these activities during the collection process. Proposed §26.93(a)(2) would permit alcohol testing to proceed if the donor states that none of the activities listed in §26.93(a)(1) had occurred, while proposed §26.93(a)(3) would retain the current requirement for a 15-minute waiting period before a donor could be tested if he or she had engaged in the activities listed in proposed §26.93(a)(1). Proposed §26.93(a)(4) would add a requirement for the collector to explain that it is to the donor's benefit to avoid the activities listed in §26.93(a)(1) during the collection process. Proposed §26.93(a)(5) would add a requirement for the collector to explain to the donor that initial and confirmatory alcohol tests will be conducted at the end of the waiting period regardless of whether the donor has engaged in any of the activities listed in §26.93(a)(1). Proposed §26.93(a)(6) would add a requirement for the collector to document that the instructions were communicated to the donor. The proposed additional requirements for the collector to communicate with the donor about the

potential effects on test results of the activities listed in proposed §26.93(a)(1) would ensure that donors clearly understand the reasons for avoiding those activities and the potential consequences of engaging in them in order to protect their rights to due process under the rule. The proposed requirement for the collector to document that the instructions were communicated to the donor would be necessary to ensure that the collector does not inadvertently omit the instructions and improve the legal defensibility of the collection procedure, should a donor challenge it.

Proposed §26.93(b) would be added to require collectors to minimize delays in administering for-cause drug and alcohol tests and complete alcohol testing before collecting a specimen for drug testing. These proposed requirements would decrease the likelihood that a donor's test results would fall below the program's cutoff levels as a result of metabolic processes over time, which could prevent the detection of proscribed alcohol consumption or drug use. Delays between the time at which a donor reports for testing and the time at which testing occurs would continue to be permitted for tests conducted under conditions other than for cause, because, in contrast to for-cause testing, there would be no reason to believe that an individual may have used drugs or alcohol in violation of the FFD policy. Therefore, there would be no basis for a concern that metabolic processes may cause inaccurate test results. The proposed provision would be consistent with the related regulations of other Federal agencies.

Section 26.95 Conducting an initial test for alcohol using a breath specimen

Proposed §26.95 [Conducting an initial test for alcohol using a breath specimen] would replace the portions of current Section 2.4(g)(18) in Appendix A to Part 26 that specify procedures for conducting an initial test for alcohol. Collectors would follow the procedures in this section when using ASDs that test breath specimens and EBTs. The proposed section

would increase the consistency of Part 26 with the procedures of other Federal agencies for workplace alcohol testing. Consistent with other agencies' procedures, the proposed rule would eliminate the requirement in current Section 2.4(g)(18) in Appendix A to Part 26 for collecting a second breath specimen for the initial alcohol test. The experience of other Federal agencies indicates that the current Part 26 requirement for two breath specimens is unnecessary to obtain a valid, reliable, and legally defensible test result, if the procedures specified in the proposed section are followed. Therefore, the proposed rule would amend the current procedures to reduce the burden on FFD programs and donors that is associated with collecting two breath specimens for the initial alcohol test, while continuing to ensure that breath alcohol testing provides accurate results.

Proposed §26.95(a) would be added to require the collector to start breath testing as soon as reasonably practical after the donor indicates that he or she has not engaged in any activities that may result in the presence of mouth alcohol or after the 15-minute waiting period, if required. The phrase, "as soon as reasonably practical," would be added to the proposed paragraph in response to stakeholder comments at the public meetings discussed in Section V. The intent of the provision is for the collector to conduct the initial alcohol test as soon as the individual has received the instructions specified in proposed §26.93 [Preparing for alcohol testing] in order to ensure the accuracy of the test result, because delays in conducting the test increase the possibility that the donor may inadvertently engage in a behavior that could result in the presence of mouth alcohol as well as permit the donor's metabolism to lower the alcohol concentration in the specimen, if the donor has consumed alcohol. However, the stakeholders noted that when preparing for outages, in which it is sometimes necessary to test large numbers of individuals, collectors often provide the instructions in proposed §26.93 to groups of donors at the same time and it is not feasible to test each one immediately after providing the

instructions. Therefore, the proposed rule would add the phrase, “as soon as reasonably practical,” to permit reasonable delays in testing associated with outage planning.

Proposed §26.95(b)(1) would permit the donor to select the mouthpiece to be used for testing, at the collector’s discretion. Permitting the donor to select the mouthpiece would not be required, but may increase the donor’s confidence in the integrity of the testing process by assuring the donor that the selection of the mouthpiece is random, if he or she is concerned that a collector would attempt to subvert the testing process by, for example, selecting a mouthpiece that had been contaminated with alcohol or other means of tampering with the testing device. The NRC is not aware of any instances in Part 26 programs in which a donor has accused a collector of altering an alcohol testing device. However, the experience of other Federal agencies who similarly require workplace alcohol testing indicates that taking steps to reduce potential donor concerns about the integrity of the testing process increases donors’ willingness to participate in the testing procedures and reduces the potential for legal challenges.

Proposed §26.95(b)(2) would instruct the collector to open the mouthpiece packaging and insert it into the device in view of the donor. The proposed requirement to insert the mouthpiece into the device in the view of the donor would be added for the same reason described with respect to proposed §26.95(b)(1).

Proposed §26.95(b)(3) would require the donor to blow into the mouthpiece for at least 6 seconds in order to obtain an adequate breath sample. The requirement to obtain the specimen from the end of the breath exhalation in current Section 2.4(g)(18) in Appendix A to Part 26 would be deleted as unnecessary based upon improvements to breath-testing technology.

Proposed §26.95(b)(4) would require the collector to show the test result to the donor. This proposed requirement is consistent with current industry practices and is intended to increase donor confidence in the integrity of the testing process by ensuring that both the donor and the collector have access to the same information about the donor's test result. The proposed requirement is consistent with Goal 7 of this rulemaking, which is to protect the due process rights of individuals who are subject to Part 26, by ensuring that donors are aware of the information used by the collector to determine whether an alcohol test result is positive or negative.

Proposed §26.95(b)(5) would require the collector to ensure that the test result record can be associated with the donor and is maintained secure, consistent with the many provisions throughout the current and proposed rules that the chain-of-custody must be maintained for specimens and the associated documentation of test results. Proposed §§26.129 and 26.159 [Assuring specimen security, chain of custody, and preservation] would establish similar requirements for urine specimens at licensee testing facilities and HHS-certified laboratories, respectively.

Proposed §26.95(c) would be added to require the collection of only one breath specimen for the initial test, unless problems in the collection require that the collection must be repeated. Problems in the collection may include, but would not be limited to, device malfunctions or a donor's inability to provide an adequate breath specimen on the first try. If a repeat collection is required, the collector would rely on the result from the first successful collection in determining the need for confirmatory alcohol testing. If the procedures specified in this proposed section are followed, relying on one breath specimen for the initial test, rather than the two required in the current rule, would increase the consistency of Part 26 collection procedures with those of other Federal agencies, consistent with Goal 1 of this rulemaking.

The proposed provision would also reduce the time required for breath specimen collections without compromising the accuracy, validity, or reliability of the test results. Therefore, the proposed provision would also meet Goal 3 of this rulemaking, which is to improve the efficiency of FFD programs.

Section 26.97 Conducting an initial test for alcohol using a specimen of oral fluids

A new §26.97 [Conducting an initial test for alcohol using a specimen of oral fluids] would establish requirements for conducting initial alcohol tests using an ASD for testing oral fluids specimens. The proposed rule would permit licensees and other entities to rely on ASDs that test oral fluids for the reasons discussed with respect to proposed §26.83(a). The proposed procedures for conducting alcohol testing with an ASD for testing oral fluids would incorporate the related requirements from 49 CFR Part 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs" (65 FR 41944; August 9, 2001) and would be added to the proposed rule to ensure that initial alcohol tests of oral fluids provide accurate and legally defensible test results.

Proposed §26.97(a) would be added to specify the procedures that the collector would follow in using an ASD for testing oral fluids, as follows:

Proposed §26.97(a)(1) would require the collector to check the expiration date on the device and show it to the donor. Some devices degrade during storage. Therefore, this step would be necessary to assure both the donor and the collector that the device can be expected to function properly.

Proposed §26.97(a)(2) would require the collector to open an individually wrapped or sealed package containing the device in the presence of the donor. The proposed rule would

add the requirement for the collector to open the package in the presence of the donor for the reasons discussed with respect to proposed §26.95(b)(1).

Proposed §26.97(a)(3) would require the collector to offer the donor a choice of using the device or having the collector use it. If the donor chooses to use the device, the collector would be required to provide instructions for its proper use. The proposed rule would require the collector to offer the donor the choice of using the device to increase the donor's confidence in the integrity of the testing process, as discussed with respect to proposed §26.95(b)(1).

Proposed §26.97(a)(4) would require the collector to gather oral fluids in the proper manner if the donor chooses not to use the device, or in cases in which a second test is necessary because the device failed to activate. In addition, the collector would be required to wear single-use examination or similar gloves while doing so and change them following each test. Proposed §26.97(a)(5) would require the collector to follow the manufacturer's instructions to ensure that the device has activated. The proposed requirements in these paragraphs to follow the device manufacturer's instructions for collecting the specimen and verify that the device has activated would be added to ensure that the collection is properly conducted. The proposed requirement to use single-use examination gloves would ensure that the collector and donor are protected from possible infection from exposure to body fluids.

Proposed §26.97(b) would be added to specify the procedures that the collector would follow if the first attempt to conduct the test using the ASD fails for any reason, including, but not limited to, the ASD failing to activate or the device is dropped on the floor.

Proposed §26.97(b)(1) would require the collector to discard the device and conduct another test using a new device that has been under the collector's control if the first attempt fails. The proposed rule would require the second device used to have been under the collector's control to ensure that there have been no opportunities for the donor or another

individual to substitute the new device with another that has been altered to provide a false negative test result. This proposed requirement would be necessary to protect the integrity of the collection process.

Proposed §26.97(b)(2) would require the collector to record the reason for the new test. The proposed rule would require documentation of the reason for the new test to ensure that the information is available, should any questions arise with respect to the collection procedure in a review conducted under proposed §26.39 [Review process for fitness-for-duty policy violations] or legal proceedings.

Proposed §26.97(b)(3) would require the collector to offer the donor the choice of using the device or having the collector use it, unless the collector concludes that the donor was responsible for the new test needing to be conducted. The proposed rule would require the collector to offer the donor the choice of using the device for the reasons discussed with respect to proposed §26.95(b)(1). The requirement for the collector to use the device if he or she concludes that the donor was responsible for the second test needing to be conducted would enhance the efficiency of the collection procedure by ensuring that the second collection is conducted properly.

Proposed §26.97(b)(4) would require the collector to repeat the collection procedures outlined in proposed §26.97(a) for the second collection.

If the second collection attempt fails, proposed §26.97(c) would be added to direct the collector to use an EBT to perform the initial alcohol test instead. The proposed rule would require the collector to use an EBT to perform the initial test after two failed attempts at testing oral fluids specimens to ensure that a valid test result is obtained to enhance the efficiency of the collection procedure by changing the method used to conduct the test.

If the specimen collection using the ASD for testing oral fluids is successful, proposed §26.97(d) would instruct the collector to follow the device manufacturer's instructions for reading the result and show the result to the donor. The proposed rule would prohibit the collector from reading the result sooner than instructed by the device manufacturer because some devices require several minutes after specimen collection to provide an accurate result, but no more than 15 minutes in all cases. The proposed requirement for the collector to show the test result to the donor is intended to increase donor confidence in the integrity of the testing process by ensuring that both the donor and the collector have access to the same information about the donor's test result. The proposed paragraph would also require the collector to record the test result and that an ASD was used to document the collection and test and ensure that the information is available, should any questions arise with respect to the collection procedure in a review conducted under proposed §26.39 [Review process for fitness-for-duty policy violations], or legal proceedings.

In order to protect collectors and donors from any possible biohazards, proposed §26.97(e) would be added to prohibit the reuse of any devices, swabs, gloves, and other materials used in collecting oral fluids.

Section 26.99 Determining the need for a confirmatory test for alcohol

A new §26.99 [Determining the need for a confirmatory test for alcohol] would amend the existing requirements in current §26.24(g) and the portion of Section 2.7(e)(1) in Appendix A to Part 26 that addresses cutoff levels for alcohol testing. The proposed rule would amend the current requirements for consistency with a new approach to determining positive alcohol test results in proposed §26.103 [Determining a confirmed positive test result for alcohol]. The proposed approach would be adopted because some licensees have not taken

appropriate action when a donor has obtained alcohol test results just below the current 0.04 percent BAC cutoff level after the donor has been at work for several hours. A BAC below 0.04 percent after the donor has been at work for several hours allows very little doubt that the donor has had an unacceptably high BAC, and has probably been impaired, at some time during the work period. Therefore, new cutoff levels for alcohol testing would be established in proposed §§26.99 and 26.103 that would take into account the average rate at which individuals metabolize alcohol over time. In proposed §26.99(a), the cutoff level for the initial alcohol test result would be decreased from 0.04 to 0.02 percent BAC and a confirmatory alcohol test would be required if a donor's initial test result is 0.02 percent BAC or higher. In addition, in proposed §26.99(b), the collector would be required to record the time at which the initial alcohol test result is obtained, so that the length of time during which the donor has been in a work status could be calculated to determine whether a confirmatory test result is positive, in accordance with proposed §26.103. The proposed changes in the initial alcohol test cutoff level and testing procedure are necessary to support the provisions of proposed §26.103, which would require the collector to declare an alcohol test as positive if the donor’s confirmatory test result is 0.03 percent or higher after the donor has been on duty for one hour, or 0.02 percent or higher after the donor has been on duty for 2 hours. The revised lower cutoff level for the initial test of 0.02 percent BAC would permit licensees and other entities to identify donors who have had a BAC of 0.04 percent or higher while in a work status, and to initiate confirmatory testing for those individuals.

Section 26.101 Conducting a confirmatory test for alcohol

A new §26.101 [Conducting a confirmatory test for alcohol] would be added to provide detailed procedures for conducting confirmatory breath alcohol tests. These proposed

procedures would incorporate the related requirements from 49 CFR Part 40, “Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs” (65 FR 41944; August 9, 2001), which would be added to the proposed rule to ensure that confirmatory breath alcohol tests provide accurate and legally defensible test results when using the EBTs that would be required in proposed §26.91(b) [Acceptable evidential breath testing devices] and relying upon one breath specimen for confirmatory testing, as would be required in proposed paragraph (c) of this section.

Proposed §26.101(a) would require licensees and other entities to conduct the confirmatory test as soon as possible following the initial alcohol test, and in all cases, no later than 30 minutes after the initial test. The proposed rule would add this requirement to reduce the possibility that alcohol metabolism will cause a confirmatory test to provide a result falling below the applicable cutoff level. Current Section 2.4(g)(18) in Appendix A to Part 26 does not require that confirmatory testing must be conducted as soon as possible after a positive initial alcohol test result is obtained, although licensees follow this practice. However, the 30-minute limit would be added because some FFD program personnel may be tested under DOT procedures, as permitted in proposed §26.31(b)(2), and an EBT that is suitable for confirmatory testing may not be immediately available at the collection site, such that transport to another collection site is required. The 30-minute interim period would be unnecessary at licensees’ and other entities’ collection sites because licensees’ and other entities’ collection sites would have the capability to conduct confirmatory tests with an EBT, as required under proposed §26.87(a). Therefore, except in these unusual circumstances, licensees and other entities would be expected to continue their current practice of conducting the confirmatory test immediately after a donor’s initial test result is determined to be positive.

Proposed §26.101(b) would be added to specify procedures for conducting a confirmatory alcohol test.

Proposed §26.101(b)(1) and (b)(2) would require the collector to conduct an air blank before beginning the confirmatory test and verify that the air blank reading is 0.00. These proposed steps are necessary to ensure that the EBT is functioning properly before the test begins.

Proposed §26.101(b)(3) would require the collector to take the EBT out of service if a second air blank test reading is above 0.00. This proposed step is necessary because a reading above 0.00 on an air blank test indicates that the EBT is not functioning properly and may provide inaccurate test results.

Proposed §26.101(b)(4)–(b)(7) would be added to specify requirements for handling the EBT's mouthpiece; reading the test number displayed on the EBT; blowing into the EBT; and showing, recording, and documenting the result displayed on the EBT, respectively. The necessity for these steps would be the same as for those discussed with respect to the related steps in proposed §26.95 [Conducting an initial test for alcohol using a breath specimen]. However, the proposed rule would not permit the donor to insert the mouthpiece into the EBT for the confirmatory test, because it is necessary to ensure that the confirmatory test is conducted strictly in accordance with the proper procedures to produce a result that meets evidential standards. Meeting evidential standards would be necessary if any questions arise with respect to the collection procedure in a review conducted under proposed §26.39 [Review process for fitness-for-duty policy violations], or legal proceedings.

Proposed §26.101(c) would be added to require that only one breath specimen must be collected for the confirmatory alcohol test, unless problems in the collection require that the collection be repeated. If a repeat collection is required, the collector would rely upon the result

from the first successful collection in determining the confirmatory test result. As discussed with respect to proposed §26.95(c), if the procedures specified this proposed section are followed, relying on one breath specimen for the initial test, rather than the two required in the current rule, would increase the consistency of Part 26 collection procedures with those of other Federal agencies, and reduce the time required for breath specimen collections without compromising the accuracy, validity, or reliability of the test results. The proposed paragraph would also prohibit licensees and other entities from combining or averaging results from more than one test in order to arrive at the confirmatory test result. These calculations, which are required in current Section 2.4(g)(18) in Appendix A to Part 26, would no longer be necessary with use of the EBTs specified in proposed §26.91(b). The proposed change would meet Goal 3 of this rulemaking, which is to improve the efficiency of FFD programs.

Proposed §26.101(d) would amend the portion of current Section 2.4(g)(18) in Appendix A of Part 26 that requires using a different EBT for conducting the confirmatory alcohol test than the EBT that the collector used for initial alcohol testing. The proposed rule would permit the use of the same EBT for both initial and confirmatory alcohol testing, rather than require the use of two different EBTs. The licensee or other entity would obtain one breath specimen for initial alcohol testing and one for confirmatory testing, if necessary, but would be permitted to conduct both tests using the same EBT. This proposed change would be made because improvements in EBT technology assure that valid and reliable test results may be obtained from a single EBT, if the proposed specimen collection and quality assurance procedures in this part are followed. Reducing the number of breath specimens required for alcohol testing would not only reduce the costs associated with alcohol testing, but would also reduce the burden on donors that is imposed by the collection process. Use of the same EBT

for initial and confirmatory testing is consistent with the procedures of other Federal agencies for workplace alcohol testing.

Section 26.103 Determining a confirmed positive test result for alcohol

A new §26.103 [Determining a confirmed positive test result for alcohol] would amend the current cutoff level for determining whether a confirmatory alcohol test result is positive, as specified in current §26.24(g) and Section 2.7(f)(2) in Appendix A to Part 26. The proposed rule would establish new cutoff levels that take into account the length of time the donor has been in a work status for the reasons discussed with respect to proposed §26.99 [Determining the need for a confirmatory test for alcohol]. Proposed §26.103(a)(1) would retain the 0.04 percent BAC in current §26.24(g) and Section 2.7(f)(2) in Appendix A to Part 26 as the cutoff level for a confirmed positive alcohol test result at any time, regardless of the length of time the donor has been in a work status. Proposed §26.103(a)(2) and (a)(3) would establish new cutoff levels for positive alcohol test results that are above the 0.02 percent BAC cutoff level on the initial test and do not meet or exceed the 0.04 percent BAC cutoff level upon confirmatory testing, but indicate that the donor had a BAC of 0.04 percent or greater while in a work status or had consumed alcohol while on duty. The cutoff levels and time periods in proposed §26.103(a)(2) and (a)(3) are based upon the average rate at which normal metabolic processes reduce an individual's BAC over time, which is about 0.01 percent BAC per hour. Therefore, a donor whose BAC is measured as 0.03 percent after the donor has been in a work status for one hour would have had a BAC of approximately 0.04 percent when he or she reported for work an hour ago. Through the same metabolic processes, a donor whose BAC is measured as 0.02 percent after he or she has been in a work status for 2 hours would also have had a BAC of approximately 0.04 percent when he or she reported for work 2 hours ago. These

proposed changes would improve the effectiveness of FFD programs by ensuring that confirmatory alcohol testing identifies donors who have been impaired from alcohol use while on duty and, therefore, may have posed a risk to public health and safety.

Proposed §26.103(b) would be added to strengthen FFD programs by requiring licensees and other entities to address circumstances in which a donor's confirmatory alcohol test result is greater than 0.01 percent BAC when the individual has been in a work status for 3 hours or more, but his or her BAC falls below the cutoff levels in proposed §26.103(a). The proposed rule would require the collector to declare the test as negative because some of the EBTs that licensees and other entities would be permitted to use for confirmatory alcohol testing under the proposed rule have not been thoroughly evaluated by NHTSA for accurately estimating BAC levels below 0.02 percent. However, if an individual has an alcohol test result above 0.01 percent BAC, and has been in a work status for 3 hours or more, the test result would provide a reason to believe that the individual has been impaired while on duty. Therefore, the proposed provision would require the licensee or other entity to ensure that the donor's alcohol use is evaluated, a determination of fitness is performed, and that the results of the determination of fitness indicate that the donor is fit to safely and competently perform his or her duties before the individual is permitted to perform the duties that require him or her to be subject to this part after testing. This proposed change would strengthen the effectiveness of FFD programs by ensuring that the alcohol use of individuals who may have been impaired when reporting for duty is assessed to determine whether such individuals' alcohol use is problematic and may pose a future risk to public health and safety and the common defense and security.

Current Section 2.4(g)(19) in Appendix A to Part 26, which establishes requirements for collecting a blood specimen for alcohol testing, would be deleted in its entirety because blood

testing for alcohol, at the donor's discretion, would no longer be permitted in the proposed rule. The reasons for eliminating blood testing for alcohol from the proposed rule discussed with respect to proposed §26.83(a).

Section 26.105 Preparing for urine collection

A new §26.105 [Preparing for urine collection] would be added to describe the preliminary steps for collecting a urine specimen for drug testing. This proposed section would reorganize the requirements in current Section 2.4(g)(5)–(g)(7) in Appendix A to Part 26 by separating alcohol and urine specimen collection procedures into separate sections of the proposed rule for organizational clarity. The proposed section would also establish several new requirements that would be added to meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.105(a) would revise current Section 2.4(g)(5) in Appendix A to Part 26, which requires the donor to remove any unnecessary outer garments and belongings that might conceal items or substances that could be used to tamper with a urine, breath, or blood specimen. The proposed paragraph would eliminate the references to blood and breath specimens in the current paragraph. Reference to blood specimens would be eliminated because blood testing for alcohol, at the donor's discretion, would no longer be permitted in the proposed rule, as discussed with respect to proposed §26.83(a). Reference to breath specimens would be eliminated in the proposed paragraph because the proposed rule would present requirements related to preparing for alcohol testing in a separate section, proposed §26.93 [Preparing for alcohol testing], for organizational clarity.

Proposed §26.105(b) would be added to require the donor to empty his or her pockets and display the items contained in them. The proposed requirement for the collector to examine the contents of the donor's pockets would increase the likelihood of detecting items (e.g., a vial of powdered urine, bleach, a portable heating unit, a false penis or any other tube or device that may be used to replicate the function of urinary excretion) that could be used to adulterate or substitute the specimen in a subversion attempt. The collector would be required to use his or her judgment in determining whether an item found in the donor's pockets indicates a clear intent to attempt to subvert the testing process. For example, whereas a container of urine found in a donor's pocket would be clear evidence of an intent to subvert the testing process, a container of eye drops, which could be used to adulterate the specimen, would, in most cases, be unlikely to indicate an intent to subvert the testing process. Should the collector identify an item that indicates a possible intent to subvert the testing process, the proposed paragraph would require him or her to contact the FFD program manager or MRO in order to obtain direction regarding the need for a directly observed collection. If the collector identifies an item that could be used to tamper with the specimen, but does not indicate an intent to subvert testing, then the collector would secure the item and continue with the collection. These proposed requirements would be added to meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, as well as Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs, by improving the ability of the collector to identify attempts to subvert the drug testing process. The proposed requirement for the donor to permit the collector to make this examination would be added in response to stakeholder requests at the public meetings discussed in Section V to ensure that donors understand that they must cooperate with the examination.

Proposed §26.105(c) would retain current Section 2.4(g)(6) in Appendix A to Part 26, which requires the individual to be instructed to wash his or her hands prior to urination. The proposed rule would make two minor editorial changes to the current provision for clarity in the language of the proposed rule. The proposed rule would clarify that the collector is to instruct the donor to wash and dry his or her hands and would replace the term, “individual,” with the term, “donor.”

Proposed §26.105(d) would retain current Section 2.4(g)(7) in Appendix A to Part 26, which requires the donor to remain in the presence of the collection site person and not to have access to any source of water or other materials that could be used to tamper with the specimen. The proposed rule would make two minor editorial changes to the current provision for clarity in the language of the rule. The proposed rule would replace the term, “collection site person,” with the simpler term, “collector,” and the term, “individual,” with the term, “donor.”

Proposed §26.105(e) would be added to permit the donor, at the collector’s discretion, to select the specimen collection container that he or she will use. Permitting the donor to select the collection kit would not be required, but may increase the donor’s confidence in the integrity of the testing process by assuring the donor that the selection of the collection kit is random, if he or she is concerned that a collector would attempt to subvert the testing process by, for example, selecting a kit that had been contaminated with a substance that would produce a positive or adulterated test result in order to entrap the donor. The importance of providing assurance to the donor regarding the integrity of the collection process is discussed with respect to proposed §26.95(b)(1). The proposed paragraph would also prohibit the donor from taking collection kit materials (such as the specimen label) other than the collection container into the private area used for urination in order to ensure that a donor could not tamper with the other collection kit materials and thereby disrupt the chain of custody for the

urine specimen. The proposed paragraph would be consistent with the related requirements of other Federal agencies and so would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.107 Collecting a urine specimen

Proposed §26.107 [Collecting a urine specimen] would amend current Section 2.4(g)(8), (g)(9), and (g)(12) in Appendix A to Part 26 to update Part 26 urine specimen collection procedures and incorporate advances in other relevant Federal rules and guidelines, consistent with Goal 1 of this rulemaking.

Proposed §26.107(a)(1) would be added to specify the instructions that the collector would be required to provide to the donor. The proposed paragraph would require the collector to instruct the donor to go into the room or stall used for urination, provide a specimen of the quantity that has been predetermined by the licensee or other entity, not flush the toilet, and return with the specimen as soon as the donor has completed the void. The proposed rule would require the collector to provide these instructions to the donor so that the donor would understand his or her responsibilities with respect to the urine collection procedure. In addition, the instructions would be necessary to implement other provisions of the proposed rule, as follows: The quantity of urine that the collector would instruct the donor to provide would be based upon the requirements of the licensee's or other entity's drug testing program, as discussed with respect to proposed §26.109 [Urine specimen quantity]. The collector would instruct the donor not to flush the toilet so that the collector may inspect the private area in which the donor voided after receiving the specimen, as discussed with respect to proposed paragraph (c) of this section. The collector would instruct the donor to return with the specimen

as soon as the donor has completed the void in order to minimize the possibility that the urine specimen would cool and its temperature would fall below the acceptable specimen temperature range specified in proposed §26.111(b).

Proposed §26.107(a)(1) would further amend current Section 2.4(g)(8) in Appendix A to Part 26, which states that the individual may provide his/her urine specimen in the privacy of a stall or otherwise partitioned area that protects individual privacy. For clarity, the proposed paragraph would replace “may” in the current rule with “shall” to indicate that the area in which the donor will urinate must provide for individual privacy. The proposed rule would also add an exception to the current requirement for privacy in the case of a directly observed collection. This proposed change would be made for greater accuracy in the language of the rule, because the requirement for individual privacy would not apply in the case of a directly observed collection, as discussed with respect to proposed §26.115 [Collecting a urine specimen under direct observation].

Proposed §26.107(a)(2) would be added to further emphasize the requirement in current Section 2.4(g)(8) in Appendix A to Part 26 that donors must be provided with individual privacy when providing a urine specimen. The proposed paragraph would require that, unless the specimen is to be collected under direct observation, no one other than the donor may go into the private area in which the donor will urinate. Although the NRC is not aware of any instances in Part 26 programs in which the current requirement for individual privacy has been compromised, the experience of other Federal agencies has indicated that such emphasis is necessary.

Proposed §26.107(a)(3) would permit the collector to set a reasonable time limit for the donor to urinate. Rather than establishing a specific time limit, the proposed rule would permit the collector to rely on his or her professional judgment in order to ensure that individuals who

may experience difficulty in voiding have sufficient time to provide a specimen, while also permitting collectors to prevent donors from disrupting the testing process by taking an unduly long time to provide a specimen. Proposed training and qualification requirements to ensure that collectors are able to exercise professional judgment appropriately would be specified in proposed §26.85 (a). At the public meetings discussed in Section V, stakeholders reported incidents in which donors appeared to be attempting to disrupt the testing process by spending an unduly long time providing a specimen and challenged the collector's authority to set a time limit. The proposed paragraph would clarify that collectors have the authority to set a reasonable time limit for voiding. In addition, the proposed paragraph would increase the consistency of Part 26 with the procedures implemented by other Federal agencies, consistent with Goal 1 of this rulemaking.

Proposed §26.107(b) would amend current Section 2.4(g)(9) in Appendix A to Part 26, which requires the collector to note any unusual behavior or appearance in the permanent record book and on the custody-and-control form. The proposed paragraph would clarify the intent of the current requirement, which has raised implementation questions from licensees, by specifying that the collector must pay careful attention to the donor during the collection process for the purpose of noting any conduct that may indicate an attempt to tamper with the specimen. The proposed paragraph would also provide examples of the types of behavior that may indicate a subversion attempt and require the collector to contact FFD program management if such behavior is observed. The proposed rule would require FFD program management to determine whether a directly observed collection is necessary under proposed §26.115 [Collecting a urine specimen under direct observation].

Proposed §26.107(c) would be added to specify the actions to be taken by the collector and donor to complete the specimen collection procedure. The first sentence of proposed

§26.107(c) would retain the existing instruction in current Section 2.4(g)(12) in Appendix A to Part 26, which prohibits the donor from washing his or her hands until the specimen has been delivered to the collector. The proposed paragraph would also add a requirement for the collector to inspect the private area for any evidence of a subversion attempt prior to flushing the toilet. This proposed additional requirement would be consistent with existing industry practices and the procedures of other Federal agencies. In addition, it may increase the likelihood of detecting subversion attempts from which physical evidence may remain in the toilet bowl or private area where the donor voided, which could include, but would not be limited to, an empty vial that contains an adulterant, powdered urine spilled on the floor, or the remains of an adulterant in the toilet bowel.

Section 26.109 Urine specimen quantity

A new §26.109 [Urine specimen quantity] would amend current Section 2.4(g)(11) in Appendix A to Part 26, which establishes 60 milliliters (mL) as the minimum quantity of urine that an FFD program must collect from donors and the procedures to be followed if a donor is unable to provide the specified quantity.

Proposed §26.109(a) would introduce a new term, “the predetermined quantity.” The predetermined quantity of urine that a donor would be requested to provide would be established by the licensee or other entity, depending upon the characteristics of the licensee’s or other entity’s testing program. The proposed rule would require the predetermined quantity to include at least 30 milliliters (mL) of urine, but licensees and other entities could request a larger quantity of urine, if the specimen will be initially tested at a licensee testing facility, if testing will be conducted for additional drugs beyond those required in proposed §26.31(d)(1), if

split specimen procedures will be followed, and if the licensee's or other entity's program includes some combination of these characteristics.

The proposed paragraph would establish 30 mL as the basic quantity of urine that donors must provide for a testing program that does not include initial tests at a licensee testing facility, does not test for additional drugs, and does not follow split specimen procedures. The 60 mL quantity that is required in current Section 2.4(g)(11) in Appendix A to Part 26 would be reduced to 30 mL to decrease the burden on donors, while ensuring that a sufficient quantity of urine is available to complete initial validity and drug tests, confirmatory validity and drug tests (if required), and any retests that may be requested by the donor and authorized by the MRO under proposed §26.165(b). NRC staff discussions with representatives of HHS-certified laboratories indicated that advances in testing technologies allow for these minimum testing and retesting procedures to be completed on a 30 mL specimen. Therefore, a 60 mL specimen would no longer be necessary to achieve the NRC's minimum objectives of conducting validity and drug tests on each specimen for the five classes of drugs specified in proposed §26.31(d)(1), as well as retesting of the specimen, if required.

Proposed §26.109(a) would also specify the additional quantity of urine, above the basic 30 mL, to be collected when the testing program follows split specimen procedures. Licensees and other entities would be required to collect an additional 15 mL for transfer into Bottle B of a split specimen for storage and possible testing. (As discussed with respect to proposed §26.113(b), the proposed rule would replace the terms, "primary specimen" and "split specimen," in the current rule with the terms, "Bottle A" and "Bottle B," for clarity in the language of the rule and consistency with the terminology used by other Federal agencies.) This additional 15 mL would be sufficient to permit the HHS-certified laboratory to conduct validity and drug tests of the specimen in Bottle B, at the donor's request, and is consistent with the

quantity required in the related provisions of other Federal agencies. Therefore, if a licensee's or other entity's testing program follows split specimen procedures, but does not include initial tests at the licensee testing facility or testing for additional drugs beyond those specified in proposed §26.31(d)(1), then the predetermined quantity for this testing program would be 45 mL (30 mL for basic testing + 15 mL for the split specimen). The predetermined quantity would be larger than 45 mL if the testing program also includes initial tests at a licensee testing facility and testing for additional drugs.

Proposed §26.109(a) would also permit licensees and other entities to include in the predetermined quantity the additional amount of urine that would be necessary to support testing for additional drugs beyond those specified in proposed §26.31(d)(1). Licensees and other entities would consult with the HHS-certified laboratories they use to identify the quantity of urine required to test for the additional drugs. For example, if the licensee's or other entity's testing program does not include initial tests at a licensee testing facility and does not follow split specimen procedures, then the predetermined quantity for that testing program would consist of the 30 mL basic quantity plus the additional amount of urine needed to test for additional drugs. As another example, if a licensee's or other entity's testing program includes initial tests at a licensee testing facility, follows split specimen procedures, and tests for additional drugs, then the predetermined quantity would consist of the 30 mL basic quantity plus 15 mL for the split specimen plus the additional amount required to test for additional drugs.

Proposed §26.109(a) would also permit licensees and other entities to include in the predetermined quantity the additional amount of urine that is necessary to perform initial validity and drug tests at the licensee testing facility, if initial tests are performed at the licensee testing facility. For example, one licensee testing program currently requires an additional 10 mL of urine for initial testing at the licensee testing facility, but does not test for additional drugs or

follow split specimen procedures. In this program, the predetermined quantity that collectors would request the donor to provide is 40 mL. As another example, if a licensee's or other entity's testing program includes initial tests at the licensee testing facility, does not test for additional drugs, and follows split specimen procedures, the predetermined quantity could be 55 mL (30 mL for basic testing + 15 mL for the split specimen + 10 mL for initial testing at the licensee testing facility). If this program also tests for additional drugs, the predetermined quantity could be larger than 55 mL.

Proposed §26.109(b) would be added to establish the actions that the collector must take if a donor provides a specimen that is less than the 30 mL basic quantity. NRC staff discussions with representatives of HHS-certified laboratories indicated that 30 mL is sufficient to meet the NRC's primary objectives of detecting drug use and subversion attempts through initial validity and drug testing, and for confirmatory validity and drug tests, if required, at an HHS-certified laboratory for the panel of drugs for which testing is required in proposed §26.31(d)(1). The 30 mL quantity would also ensure that sufficient urine is available for retesting the specimen for validity and for drugs and drug metabolites, should the donor request such retesting, as permitted in proposed §26.165(b). However, the 30 mL basic quantity would be insufficient to permit testing for additional drugs, initial testing at licensee testing facilities, or splitting the specimen, which are not required under this part.

Proposed §26.109(b)(1) would amend the portions of current Section 2.4(g)(11) in Appendix A to Part 26 that relate to collector actions if a donor provides an insufficient specimen. The proposed paragraph would require the collector to "encourage" the donor to drink a reasonable amount of liquid in order to provide a specimen of at least 30 mL, rather than "allow" the donor to drink additional liquid as currently required. This proposed change would be made to enhance the efficiency of FFD programs, consistent with Goal 3 of this

rulemaking, by potentially reducing the time required to obtain a specimen of the required quantity from the donor and, thereby, to complete the collection, should the donor choose to comply. However, the proposed paragraph would establish a limit on the amount of liquid that the individual would be permitted to consume to avoid the potential for "water intoxication," which is a physical response to consuming too many liquids that may cause harm to the donor. The proposed limit of 24 ounces of water over a 3-hour period would be the same limit imposed in the HHS Guidelines, and would be conservative, in order to ensure that individuals who may have a medical condition that makes them more subject to water intoxication, such as some forms of renal disease or taking some medications, would not be placed at-risk. The proposed rule would retain the current requirement in Section 2.4(g)(11) in Appendix A to Part 26 to collect successive specimens in separate containers.

Proposed §26.109(b)(2) would be added to require the collector to end the specimen collection process as soon as the donor provides a specimen of at least 30 mL in a subsequent attempt. This proposed requirement would reduce the burden on donors who may have some difficulty providing a urine specimen, while meeting the NRC's objectives of obtaining a specimen of sufficient size to support initial and confirmatory validity and drug testing, as well as retesting of the specimen.

Proposed §26.109(b)(2) would also specify that the licensee or other entity may not impose any sanctions if a donor provides a subsequent specimen that is less than the licensee's or other entity's predetermined quantity, as long as the specimen quantity is at least 30 mL. Sanctions for failing to provide sufficient urine to support initial testing at the licensee's testing facility, split specimen procedures, or testing for additional drugs would be inappropriate, because a specimen of at least 30 mL is sufficient to meet the NRC's objectives and, therefore, could not be considered a refusal to test.

Proposed §26.109(b)(2) would also require the collector to forward a subsequent specimen that is greater than 30 mL, but less than the licensee's or other entity's predetermined quantity, to the HHS-certified laboratory for testing, rather than permit the specimen to be tested at the licensee testing facility. This proposed provision is necessary to ensure that a sufficient quantity of urine is available for validity and drug testing and retesting at the HHS-certified laboratory, if required, consistent with the NRC's objectives. If the subsequent specimen is equal to or greater than the licensee's or other entity's predetermined quantity, however, the licensee or other entity would be permitted to follow the FFD program's normal testing procedures. Following normal testing procedures in this instance would be permissible because there would be sufficient urine to implement the FFD program's testing procedures (e.g., split specimen procedures, testing for additional drugs, initial testing at a licensee testing facility), while continuing to ensure that sufficient urine is available for testing and retesting at the HHS-certified laboratory, if required.

Proposed §26.109(b)(3) would be added to require the implementation of "shy bladder" procedures if a donor is unable to provide a 30 mL specimen within 3 hours of the initial attempt to provide a specimen, for the reasons discussed with respect to proposed §26.119 [Determining shy bladder]. Requirements for implementing "shy bladder" procedures would be contained in that proposed section.

Proposed §26.109(b)(4) would be added to establish additional requirements for specimen collections when a donor provides a specimen of less than 30 mL, as follows:

The proposed paragraph would eliminate the requirement in current Section 2.4(g)(11) in Appendix A to Part 26 to combine successive specimens from a donor in order to obtain a specimen of 60 mL. The proposed rule would prohibit the practice of combining specimens to ensure that successive specimens neither contaminate nor dilute a specimen that will be tested.

In addition, the proposed prohibition would increase the consistency of Part 26 with the related requirements of other Federal agencies, which is Goal 1 of this rulemaking.

Proposed §26.109(b)(4) would also require the collector to discard any specimens of less than 30 mL unless there is reason to believe that a specimen may have been altered. Examples of reasons to believe that a donor may have attempted to alter the specimen could include, but would not be limited to: (1) observation of powder (that could be an adulterant or powdered urine) spilled in the private area in which the donor urinated or on the donor's clothing; (2) unexpected sounds from the private area while the donor should be urinating, such as the sound of something being unwrapped or dropping to the floor; (3) observation that the donor's pocket appears to contain an item that was not visible before the donor entered the private area (that the donor may have previously had taped to his body); and (4) an unusual color or lack of clarity in the urine specimen. The proposed rule would require the collector to discard specimens of less than 30 mL when there is no reason to believe that the specimens had been subject to tampering because they would not be used for testing and there would be no reason to retain them.

If the collector suspects that a specimen has been altered and the suspect specimen is greater than 15 mL, the proposed rule would require the collector to forward the suspect specimen to the HHS-certified laboratory for testing, consistent with current Section 2.4(g)(16) in Appendix A to Part 26. NRC staff discussions with representatives of HHS-certified laboratories indicate that 15 mL is the minimum quantity necessary for HHS-certified laboratories to perform the initial and confirmatory (if necessary) validity and drug testing required in this part, although it would be insufficient to support retesting of the specimen at the donor's request. In these circumstances, in which the collector has observed donor conduct or specimen characteristics that indicate there is a reason to believe that the donor may have

altered the specimen, the NRC's interest in assuring that the testing process is not subverted would take precedence over the individual's ability to request retesting of the specimen. Any results of validity testing that confirm that the specimen was adulterated or substituted, in combination with the collector's observations, would provide clear evidence that a donor had tampered with the specimen and had thereby attempted to subvert the testing process.

The proposed paragraph would also amend current Section 2.4(g)(17) in Appendix A to Part 26, which requires a directly observed collection whenever there is a reason to believe that a donor has or may attempt to alter a specimen. The proposed paragraph would require the collector to contact FFD program management to determine whether a directly observed collection is required, but would not require a directly observed collection. At the public meetings discussed in Section V, the stakeholders requested flexibility in the decision to collect another specimen under direct observation. They noted that there have been numerous instances in which a collector identified incontrovertible evidence that the donor intended to or had tampered with a specimen and that, in such cases, drug testing would not provide additional information that justifies the costs associated with conducting a directly observed collection and testing the additional specimen. The NRC believes that the presence of drugs and drug metabolites in a specimen that is collected under direct observation would establish a clear motive for an alleged attempt to tamper with a specimen and would add further evidence supporting the imposition of sanctions on the donor for attempting to subvert the testing process. However, the NRC agrees with the stakeholders that such additional evidence is unnecessary when there is incontrovertible evidence that the donor intends to or has attempted to tamper with a specimen. Therefore, the proposed rule would permit FFD program management to determine whether an additional specimen collection under direct observation would be conducted. This proposed change would be made to meet Goal 3 of this rulemaking,

which is to improve the efficiency of FFD programs, by reducing the number of directly observed collections required under the rule.

Section 26.111 Checking the validity of the urine specimen

A new §26.111 [Checking the validity of the urine specimen] would amend current requirements for assessing specimen validity at the collection site, which appear in Section 2.4(g)(13)–(g)(17) in Appendix A to Part 26. In general, the changes contained in the proposed section would be made to meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.111(a) would amend current Section 2.4(g)(13) in Appendix A to Part 26, which requires the collector to measure the temperature of the specimen immediately after the urine specimen is collected. The proposed paragraph would require the collector to measure the temperature of any specimen that is 15 mL or more. The proposed rule would not require measuring the temperature of smaller specimens because the collector would be required to discard them, as discussed with respect to proposed §109(b)(4). The proposed paragraph would also amend the third sentence of current Section 2.4(g)(13) to indicate that, if the ambient temperature is low or the specimen is small, it may be necessary to measure the specimen temperature sooner than 4 minutes after the collector receives the specimen from the donor. A low ambient temperature could cool the specimen more rapidly than normal room temperatures, resulting in an inaccurate temperature reading. Specimens of less than 30 mL will cool more rapidly than specimens of 30 mL or more, so that smaller specimens may also produce inaccurate temperature readings. Therefore, the proposed rule would add an

admonition for the collector to expedite the temperature measurement process if the collection is occurring in an environment below normal room temperatures or the specimen is small.

Proposed §26.111(b) would replace current Section 2.4(g)(14) in Appendix A to Part 26, which establishes the acceptable specimen temperature range and requires conducting a second specimen collection under direct observation if a specimen's temperature falls outside the acceptable range. The proposed rule would increase the range of acceptable specimen temperatures from 90.5EF–99.8EF in the current provision to 90EF–100EF for consistency with the temperature range specified in the HHS Guidelines. The proposed wider acceptable temperature range would provide increased protection against false low or false high temperature readings and, therefore, would protect donors from the imposition of sanctions based upon inaccurate specimen temperature readings. The proposed paragraph would retain the requirement in the current rule for the collector to offer the donor the opportunity to provide a measurement of body temperature, but a measure of oral temperature would no longer be specified. New technologies for obtaining body temperature, such as digital measurement in the ear canal, would also be permitted, because the new technologies provide results more quickly that are at least as accurate as oral thermometers. The portion of current Section 2.4(g)(14) that specifies collector actions if there is a reason to believe that the individual may have tampered with the specimen would be moved to proposed §26.111(d) for organizational clarity.

Proposed §26.111(c) would amend current Section 2.4(g)(15) in Appendix A to Part 26, which requires the collector to inspect the specimen's color, determine whether there are any signs of contaminants, and record any unusual findings in the permanent record book. The proposed rule would amend this requirement by deleting reference to the permanent record book and requiring the collector to use the custody-and-control form for recording this

information. This change would be made because the proposed rule would no longer require collection sites to maintain a permanent record book, consistent with the elimination of the requirement to maintain a permanent record book in the HHS Guidelines. The proposed rule would also make minor editorial revisions to the current provision by incorporating the related language from the HHS Guidelines. These proposed changes would be made to meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with the regulations of other Federal agencies.

Proposed §26.111(d) would replace and revise the first sentence of current Section 2.4(g)(14) in Appendix A to Part 26, which requires a second specimen to be collected under direct observation if the temperature of the first specimen submitted by a donor falls outside of the acceptable specimen temperature range. The proposed paragraph would eliminate the requirement for a second specimen collection under direct observation if the specimen temperature falls outside of the required range, although licensees and other entities could, at their discretion, continue this practice. Instead, the proposed provision would require the collector to contact the FFD program manager, if the collector has a reason to believe the donor has attempted to subvert the testing process based upon observed donor behavior, the specimen temperature, unusual specimen characteristics, or other observations. The FFD program manager, at his or her discretion, would consult with the MRO to determine whether the collector's observations provide sufficient evidence that a subversion attempt has occurred to warrant the imposition of sanctions. If the MRO and/or FFD program manager determine that a subversion attempt has occurred on the basis of the collector's observations, the licensee or other entity would be permitted to impose the sanctions for a subversion attempt in proposed §26.75(b) without conducting a directly observed collection. However, at the FFD program manager's or the MRO's discretion, a second specimen may be collected under direct

observation. The proposed rule would permit the second specimen to be collected under direct observation to provide further information to assist the MRO in determining whether or not a subversion attempt has occurred. For example, positive drug test results from a second specimen that was collected under direct observation would provide additional evidence that the donor had attempted to tamper with his or her first specimen to hide drug use. This proposed change would be made in response to stakeholder requests, for the reasons discussed with respect to proposed §26.109(b)(4).

Proposed §26.111(e) would revise current Section 2.4(g)(16) in Appendix A to Part 26, which requires that all urine specimens that are suspected of being adulterated or diluted must be forwarded to the HHS-certified laboratory for testing. The proposed paragraph would add suspicion that a specimen has been substituted as a third reason for forwarding the specimen to the HHS-certified laboratory. As discussed with respect to proposed §26.31(d)(3)(i), substitution entails replacing a valid urine specimen with a drug-free specimen. This proposed addition would be made for consistency with the addition of substitution to the proposed rule as another method of attempting to subvert the testing process for which licensees and other entities would be required to impose sanctions, as discussed with respect to proposed §26.75(b).

The proposed paragraph would also specifically prohibit testing the suspect specimen at a licensee testing facility for three reasons, which are to: (1) limit the potential for specimen degradation during the time period required to conduct testing at the licensee testing facility; (2) decrease the time required to obtain confirmatory validity test results if the specimen, in fact, has been altered; and (3) ensure that a sufficient quantity of urine is available for conducting validity tests at more than one HHS-certified laboratory if, for example, the specimen contains a new adulterant or an adulterant that the licensee's or other entity's primary laboratory is not

capable of identifying [see proposed §26.161(g)]. Only suspect specimens of 15 mL or more would be sent for testing, rather than all specimens. This proposed lower limit on specimen quantity would be added in order to ensure that there would be sufficient urine available for the HHS-certified laboratory to conduct all of the validity and drug tests on the specimen that would required under this part.

Proposed §26.111(f) would require collectors and the HHS-certified laboratory to preserve as much of the specimen as possible. This proposed requirement would be added to provide increased assurance that a sufficient quantity of urine would be available to support further testing, in the event that further testing of the specimen is necessary, and to enhance the consistency of Part 26 with the related provisions of other Federal agencies.

Proposed §26.111(g) would be added to inform donors and collectors of the characteristics of a specimen that is acceptable for testing at an HHS-certified laboratory. The proposed paragraph would incorporate the related provision from the HHS Guidelines.

26.113 Splitting the urine specimen

Proposed §26.113 [Splitting the urine specimen] would update the requirements in current Sections 2.4(g)(20) and 2.7(j) in Appendix A to Part 26, which address collection site procedures for split specimens, and group them together in one section within the proposed rule for organizational clarity.

Proposed §26.113(a) would retain the first sentence of current Section 2.7(j) in Appendix A to Part 26, which permits licensees to follow split specimen procedures. The proposed rule would revise the current sentence in the active voice for increased clarity in the language of the rule.

Proposed §26.113(b) would be added to group together in one paragraph, for organizational clarity, the steps that the collector and donor must follow for the split-specimen collection procedure, which are embedded in current Section 2.4(g)(20) and portions of Section 2.7(j) in Appendix A to Part 26. The proposed rule would also replace the terminology used in the current rule that refers to the split specimen as an "aliquot," and use the terms, "Bottle A" and "Bottle B," to refer to the primary and split specimen, respectively. This proposed change would be made for increased clarity in the language of the rule and consistency with the terminology used in other relevant Federal rules and guidelines.

Proposed §26.113(b)(1) would require the collector to instruct the donor to urinate into either a specimen bottle or a specimen container. This step would be added to clarify that the donor is not required to divide a specimen into Bottle A and Bottle B while urinating. The proposed paragraph would incorporate the related provision in the HHS Guidelines.

Proposed §26.113(b)(2) would amend the portions of current Section 2.7(j) in Appendix A to Part 26 that specify the amount of urine to be contained in the split specimen bottles. The proposed rule would replace the implied requirements in the second and third sentences of Section 2.4(j), which refer to the split specimens as "halves" of the specimen that was collected, with updated requirements that would be consistent with those established in proposed §26.109 [Urine specimen quantity] and the related provisions in the HHS Guidelines. The proposed paragraph would require the collector to ensure that Bottle A contains 30 mL of urine and that Bottle B contains 15 mL. As discussed with respect to proposed §26.109, advances in urine testing technologies since Part 26 was first promulgated permit a reduction in the quantities of urine that must be collected from donors in order to conduct the testing that would be required under this part. Therefore, 30 mL of urine is now a sufficient quantity for

conducting all of the testing that may be required under this part, while 15 mL is sufficient for any retesting that a donor may request.

The proposed paragraph would also specify that the specimen in Bottle A would be used for drug and validity testing and that, even if there is less than 15 mL of urine available for Bottle B after the collector ensures that Bottle A contains 30 mL, the specimen in Bottle A must be subject to testing anyway. These clarifications would be added to the proposed rule because, in the experience of other Federal agencies, some collection sites have discarded any specimen of less than 45 mL and conducted another collection to obtain a sufficient amount of urine to fill both Bottles A and B. Should any Part 26 programs follow this practice, the efficiency of FFD programs would be reduced and the burden on donors from being subject to testing would be unnecessarily increased. The 30 mL quantity is sufficient to permit retesting of the specimen in Bottle A, at the donor's discretion, and, therefore, having 15 mL of urine available for Bottle B is unnecessary to ensure donors' rights to retesting. The proposed rule would incorporate these clarifications from the HHS Guidelines to ensure that Part 26 programs do not adopt this inefficient and burdensome practice.

Proposed §26.113(b)(3) would retain the portion of current Section 2.4(g)(20) in Appendix A to Part 26 that requires the donor to observe the process of splitting the specimens and maintain visual contact with the specimen bottles until they are sealed and prepared for storage or shipping.

Proposed §26.113(c) would be added to establish priorities for using the specimen that has been collected. The proposed paragraph would permit the licensee testing facility to test aliquots of the specimen at a licensee testing facility or to test for additional drugs beyond those required under proposed §26.31(d)(1), but only if the donor has provided a specimen of at least the predetermined quantity, as discussed with respect to proposed §26.109 [Urine specimen

quantity]. As discussed with respect to proposed §26.113(b)(2), the proposed rule would require the collector first to ensure that 30 mL of urine is available for Bottle A and 15 mL for Bottle B. If the donor has provided more than 45 mL of urine and the additional amount is sufficient to support testing at the licensee testing facility, testing for additional drugs, or both, the proposed rule would permit the remaining amount of urine, above the 45 mL required for Bottles A and B, to be subject to such testing. However, if the donor has provided only 45 mL of urine, the proposed rule would require that the 15 mL of urine that remains after 30 mL has been retained for Bottle A must be used for Bottle B rather than to conduct testing at the licensee testing facility or testing for additional drugs. The proposed rule would establish the priority of using the 15 mL of urine for Bottle B, rather than for testing at a licensee testing facility or additional drugs, because the FFD program has established the expectation among donors in this instance that the FFD program will follow split specimen procedures and that Bottle B will be available for retesting at the donor's request. Reserving the 15 mL of urine for Bottle B would also be consistent with the principle that would be established in the last sentences of proposed §§26.135(b) and 26.165(a)(4) that control over testing of the specimen contained in Bottle B would reside with the donor.

Section 26.115 Collecting a urine specimen under direct observation

Proposed §26.115 [Collecting a urine specimen under direct observation] would group together in one section the requirements of the proposed rule that apply to collecting a urine specimen under direct observation. This organizational change would be made because requirements that address this topic are dispersed throughout the current rule. The proposed section would also incorporate more detailed procedures for collecting specimens under direct observation, based upon related requirements from other relevant Federal rules and guidelines.

More detailed procedures are necessary because devices and techniques to subvert the testing process have been developed since Part 26 was first published that are difficult to detect in many collection circumstances, including under direct observation, such as a false penis or other realistic urine delivery device containing a substitute urine specimen and heating element that may be used to replicate urination. Therefore, the proposed changes would be made to increase the likelihood of detecting such attempts to subvert the testing process and, thereby, increase the effectiveness of directly observed collections in assuring that a valid specimen is obtained from the donor.

Proposed §26.115(a) would amend and combine current Section 2.4(f), 2.4(g)(17), and (g)(25) in Appendix A to Part 26, which establish requirements for collecting a urine specimen under direct observation. The proposed paragraph would assign responsibility for approving a directly observed collection to the MRO or FFD program manager, rather than a "higher level supervisor" of the collector in current Section 2.4(b)(25) in Appendix A to Part 26. This proposed change would ensure that the decision to conduct a directly observed collection is made by an individual who is thoroughly knowledgeable of the requirements of this part and the emphasis that the NRC places on maintaining the individual privacy of donors. The proposed change would also be consistent with revised requirements in the HHS Guidelines related to who may authorize a directly observed collection.

The proposed rule would also list the circumstances that constitute a reason to believe that a donor may dilute, substitute, adulterate, or otherwise alter a specimen, and that would, therefore, warrant the invasion of individual privacy associated with a directly observed collection, as follows:

Proposed §26.115(a)(1) would amend current Section 2.4(f)(2) in Appendix A to Part 26, which specifies that a directly observed collection may be performed if the last urine specimen

provided by donor yielded specific gravity and creatinine concentration results that are inconsistent with normal human urine. The proposed paragraph would amend the current provision in several ways.

First, the proposed rule would eliminate the limitation in the current paragraph that a specimen may be collected under direct observation if "the last urine specimen" provided by the individual yielded specific gravity and creatinine concentration results that are inconsistent with normal human urine. The proposed rule would permit a directly observed collection if the donor had presented a specimen with characteristics that are inconsistent with normal human urine "at this or a previous collection." The proposed change would be necessary for consistency with proposed §26.75(b), which would require that an individual who has subverted or attempted to subvert any test conducted under Part 26 must be subject to a permanent denial of authorization. Because proposed §26.75(b) would require permanent denial of authorization to a donor who has engaged in a subversion attempt, individuals whose last specimen had characteristics that are inconsistent with normal human urine would not be subject to further testing under the rule. However, there may be instances in which a licensee or other entity is aware that an individual has engaged in a subversion attempt under a drug testing program that is not regulated by the NRC. If the licensee or other entity is considering granting authorization under Part 26 to the individual, then a directly observed collection would be warranted to ensure that the donor did not have an opportunity to tamper with the specimen and, therefore, that drug test results would be accurate. The amended language of the proposed provision would permit collecting a specimen under direct observation in such circumstances.

Second, the proposed rule would update the current provision by replacing the specific gravity and creatinine concentration values that are included in the current paragraph with references to a urine specimen that "the HHS-certified laboratory reported as being substituted,

adulterated, or invalid to the MRO and the MRO reported to the licensee or other entity that there is no adequate medical explanation for the result." This proposed change would be made for consistency with the addition of more detailed requirements for validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The cutoff concentrations and specimen characteristics that would lead the HHS-laboratory to report a specimen as substituted, adulterated, or invalid would be specified in proposed §26.161 [Cutoff levels for validity testing]. Requirements for the MRO's review of the test results would be specified in proposed §26.185 [Determining a fitness-for-duty policy violation].

Proposed §26.115(a)(2) would combine and update current Sections 2.4(f)(1) and 2.4(g)(14) in Appendix A to Part 26, which establish that the presentation of a specimen that falls outside of the required temperature range is sufficient grounds to conduct a directly observed collection. The proposed paragraph would retain the requirement in current Section 2.4 (f)(1) in Appendix A to Part 26, which specifies that a directly observed collection may be conducted at any time the specimen's temperature falls outside of the required temperature range. However, the proposed paragraph would amend the current requirement for the collector to take an oral measure of temperature with a sterile thermometer to permit other means of measuring the donor's body temperature, for the reasons discussed with respect to proposed §26.111(a). The proposed rule would also retain the current requirement that a directly observed collection may be conducted if the specimen's temperature falls outside of the required range and the donor declines to provide a measurement of body temperature, in proposed §26.115(a)(2)(i). However, proposed §26.115(a)(2)(ii) would eliminate the current permission to conduct a directly observed collection in those instances in which the donor's body temperature does not equal or exceed that of the specimen. The proposed rule would establish a range of acceptable variability between the donor's measured temperature and the

specimen's temperature of 1EC/1.8EF. If the donor's temperature differs from the specified temperature by more than the specified amount, a directly observed collection would be permitted. This proposed change would be made for consistency with the related provision in the HHS Guidelines and to recognize that a specimen temperature that is either much higher or lower than the donor's body temperature may indicate that the donor has attempted to subvert the testing process.

Proposed §26.115(a)(3) would update current Section 2.4(f)(3) in Appendix A to Part 26, which permits a directly observed collection if a collector observes donor conduct that clearly and unequivocally demonstrates an attempt by the donor to substitute the specimen. The proposed rule would add references to attempts to dilute and adulterate a specimen, in addition to substitution, as behaviors that demonstrate a subversion attempt, consistent with the NRC's heightened concern for ensuring specimen validity in the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). As discussed with respect to proposed §26.107(b), donor conduct that clearly and unequivocally demonstrates an attempt to alter a specimen may include, but is not limited to, possession of a urine specimen before the collection has occurred; possession of a vial, or vials, filled with chemicals that are subsequently determined to be urine or an adulterant; possession of a heating element; or evidence that the coloring agent used by the licensee or other entity in a source of standing water at the collection site [see proposed §26.87(e)(1)] discolors the specimen.

Proposed §26.115(a)(4) would update current Section 2.4(f)(4) in Appendix A to Part 26, which permits directly observed collections if a donor has previously been determined to have engaged in substance abuse and the specimen is being collected as part of a rehabilitation program and/or pre-access testing following a confirmed positive test result. The proposed paragraph would update the current requirement by adding a cross-reference to proposed

§26.69 [Authorization with potentially disqualifying fitness-for-duty information], which would establish requirements for granting or maintaining the authorization of an individual about whom potentially disqualifying FFD information has been discovered or disclosed. Several provisions in proposed §26.69 would permit or require directly observed collections, including proposed §26.69(b)(5), which would require specimens to be collected under direct observation for pre-access drug testing of individuals who have been subject to sanctions under the rule. For organizational clarity, the proposed paragraph would replace the current requirement with a cross-reference to proposed §26.69, rather than repeat the applicable requirements in this section.

Proposed §26.115(b) would amend the requirement in current Section 2.4(g)(25) in Appendix A to Part 26 that the collector must obtain permission from a "higher level supervisor" before conducting a directly observed collection, as discussed with respect to proposed §26.115(a). The second sentence of the proposed paragraph would be added to require that, once the decision has been made to conduct a directly observed collection based on a reason to believe that the donor may alter a specimen, the collection must occur as soon as reasonably practical. Although the NRC is not aware of any occasions in Part 26 programs in which a directly observed collection has been unreasonably delayed, the proposed requirement would ensure that test results from the directly observed collection provide information about the presence or absence of drugs and drug metabolites in the donor's urine. If a collection is delayed for a day or more, metabolism may cause the concentration of drugs and drug metabolites in the donor's urine, if any are present, to fall below the cutoff levels established in this part or by the FFD program and, therefore, not be detected by testing. Non-negative test results from testing a specimen collected under direct observation would provide evidence to support a conclusion that the individual had attempted to subvert the testing process in order to

mask drug abuse, whereas negative test results may counter the reason to believe that the individual had attempted to subvert the testing process. Therefore, conducting the directly observed collection as soon as reasonably practical would ensure that test results from the specimen provide relevant and useful information. The proposed requirement would also be consistent with the requirements of other relevant Federal rules and guidelines.

Proposed §26.115(c) would be added to require the collector to inform the donor of the reason(s) for the directly observed collection so that the donor is aware of the nature of the concern that has initiated a directly observed collection. This proposed requirement would be added to the proposed rule for two reasons: (1) knowing the reason for a directly observed collection may increase a donor's willingness to cooperate in the procedure in order to counter the reason to believe that the donor has or may attempt to alter the specimen, and (2) informing the donor of the reason for a directly observed collection would meet Goal 7 of this rulemaking, which is to protect donors' right to due process, by ensuring that the donor is aware of the concern that has initiated the collection. The proposed paragraph would also be consistent with the requirements of other relevant Federal rules and guidelines.

Proposed §26.115(d) would be added to establish recordkeeping requirements related to the directly observed collection. The proposed paragraph would require the collector to record on the specimen's custody-and-control form that the specimen was collected under direct observation and the reason for the directly observed collection. The proposed requirement is necessary to ensure that the HHS-certified laboratory and the MRO have this information available when the specimen is tested and the MRO conducts his or her review of the test results, as would be required under proposed §26.185 [Determining a fitness-for-duty policy violation]. This information would be important, for example, in an MRO's decision to request the laboratory to test a specimen at the LOD that appeared to have been diluted, as

permitted under proposed §26.185(g)(2), in order to compare the results from testing the dilute specimen with those obtained from testing the specimen that was collected under direct observation. Non-negative test results from the dilute specimen and the presence of the same drugs or drug metabolites in the specimen collected under direct observation would provide clear evidence that the donor had diluted the first specimen in an attempt to mask drug use. The proposed paragraph would also be consistent with the requirements of other relevant Federal rules and guidelines.

Proposed §26.115(e) would retain and combine the existing requirements in Sections 1.2, 2.4(b), 2.4(g)(14), (g)(17), and (g)(25) in Appendix A to Part 26, which require that the individual who observes the specimen collection must be of the same gender as the donor. Consistent with the current requirements, the proposed rule would permit another individual of the same gender to serve as the observer if a qualified urine collector of the same gender is not available, as long as the observer receives the instructions specified in proposed §26.115(f). The proposed rule would combine the current requirements in the proposed paragraph for organizational clarity.

Proposed §26.115(f) would be added to specify the procedures that must be followed in conducting a directly observed collection. The procedures in the proposed paragraph would be followed by either a qualified collector or an individual of the same gender who may serve as the observer. These more detailed procedures are necessary because devices and techniques to subvert the testing process have been developed since Part 26 was first published that can be used under direct observation without detection. Therefore, the proposed changes would be made to increase the likelihood of detecting such attempts to subvert the testing process and, thereby, increase the effectiveness of directly observed collections in assuring that a valid specimen is obtained from the donor.

Proposed §26.115(f)(1) would be added to specify that the observer must instruct the donor to adjust his or her clothing to ensure that the area of the donor's body between the waist and knees is exposed. This proposed requirement would be added to ensure that the observer could detect the use of an anatomically correct urine delivery device.

Proposed §26.115(f)(2) would be added to specify the action to be observed during the collection. This proposed requirement would be consistent with the requirements of other Federal agencies and is intended to ensure that the urine specimen is obtained from the donor's body.

Proposed §26.115(f)(3) would be added to prohibit an observer who is not the collector from touching the specimen container. The proposed provision would be consistent with the related requirements of other Federal agencies and is intended to protect the observer from any potential claims by a donor that the observer had altered the specimen.

Proposed §26.115(f)(4) would be added to require the collector to record the observer's name on the custody-and-control form, if the observer is not the collector. The proposed requirement would be consistent with the related requirements of other Federal agencies and is intended to ensure that the observer's identity is documented, should future questions arise regarding the collection.

Proposed §26.115(g) would be added to clarify that a donor's refusal to participate in the directly observed collection would constitute a refusal to test and, therefore, would be considered to be an act to subvert the testing process, under proposed §26.75(b). Current Section 2.4(j) in Appendix A to Part 26 requires the collector to inform the MRO, and the MRO to inform licensee management, if a donor fails to cooperate with the specimen collection process, including, but not limited, to a refusal to provide a complete specimen, complete paperwork, or initial the specimen bottles. The current requirement does not specifically

mention that a refusal to participate in a directly observed collection is also an instance of a failure to cooperate. In addition, the current rule does not require the licensee or other entity to impose sanctions on a donor for refusing to be tested. Therefore, the proposed paragraph would both clarify the NRC's original intent by stating that a refusal to participate in a directly observed collection constitutes a refusal to test and update the current requirement by adding a cross-reference to the proposed sanction of permanent denial of authorization that would be required in such circumstances under proposed §26.75(b).

Proposed §26.115(h) would be added to specify the actions that a collector must take, if a directly observed collection was required, but was not performed. The collector would inform the FFD program manager or designee of the omission, who would ensure that a directly observed collection is immediately performed. Although the concentrations of any drugs, drug metabolites, or blood alcohol in the donor's specimens may fall below the cutoff levels that would be specified in this part or in the licensee's or other entity's FFD policy if several days have elapsed since the directly observed collection should have occurred, testing a specimen collected several days later would increase the likelihood of detecting any subsequent drug or alcohol use. In addition, the metabolites from using some drugs, such as marijuana, linger in an individual's body. Therefore, conducting a directly observed collection may result in detecting these metabolites. However, because elapsed time may reduce the concentrations of drugs, drug metabolites, or blood alcohol in the donor's specimens, the proposed rule would require a directly observed collection to be performed immediately. The proposed provision would use the term, "immediately," to indicate that the licensee or other entity may be required to call in the donor and a collector to perform the directly observed collection, if the donor and collectors are not on site when the oversight is identified. This proposed requirement would

increase consistency with the related requirements of other Federal agencies and is intended to provide instructions for correcting an oversight, which are not addressed in the current rule.

Section 26.117 Preparing urine specimens for storage and shipping

A new §26.117 [Preparing urine specimens for storage and shipping] would reorganize and present together in one section current requirements for safeguarding specimens and preparing them for transfer from the collection site to the licensee's testing facility or the HHS-certified laboratory for testing. This organizational change would be made because requirements that address these topics are dispersed throughout the current rule whereas grouping them together in a single section would make them easier to locate within the proposed rule.

Proposed §26.117(a) would amend current Section 2.4(g)(20) in Appendix A to Part 26, which requires the donor and collector to maintain visual contact with specimens until they are sealed and labeled. The proposed paragraph would eliminate reference to blood specimens because donors would no longer be permitted to volunteer to provide a blood specimen for alcohol testing under the proposed rule, as discussed with respect to proposed §26.83(a). The proposed paragraph would also amend the requirements in the second sentence of the current provision. Procedural requirements for observing the splitting of a specimen and sealing the split specimen bottles would be moved to proposed §26.113 [Splitting the urine specimen] for organizational clarity. However, the proposed paragraph would broaden the current requirement, which addresses only split specimens, to require the donor to observe the transfer of any specimen or aliquot that the collector transfers to a second container and the sealing of the container(s). This proposed requirement would be necessary because some FFD programs who operate licensee testing facilities may transfer an aliquot of the urine specimen to a second

container for initial testing at the licensee testing facility, while preserving the primary specimen in the first or another container. The proposed rule would require the donor to observe these actions in order to ensure that the specimen or aliquot(s) that are transferred belong to the donor and that the identity and integrity of the specimen are maintained.

Proposed §26.117(b) would retain current Section 2.4(g)(21) in Appendix A to Part 26, which requires the donor and collector to remain present while the procedures for sealing and preparing the specimen (and aliquots, if applicable) for transfer are performed.

Proposed §26.117(c) would retain the meaning of current Section 2.4(g)(22) in Appendix A to Part 26, which establishes requirements for labeling and sealing the specimen(s), but split the current requirement into several sentences for increased clarity in the language of the provision.

For organizational clarity, proposed §26.117(d) would combine current Section 2.4(g)(23) and 2.4(g)(23)(i) in Appendix A to Part 26, which require the donor to certify that the specimen was collected from him or her. However, the proposed rule would delete current Section 2.4(g)(23)(ii), which requires the donor to have an opportunity to list on the custody-and-control form any medications he or she has taken within the past 30 days, for the reasons discussed with respect to proposed §26.89(b)(3).

The proposed rule would delete current Section 2.4(g)(24) in Appendix A to Part 26, which requires the collector to enter into the permanent record book all information identifying the specimen. This requirement would be eliminated because the proposed rule would no longer require collection sites to maintain a permanent record book, consistent with the elimination of the requirement to maintain a permanent record book in the HHS Guidelines. Collection sites would be permitted to use other means of tracking specimen identity, including, but not limited to bar coding.

Proposed §26.117(e) would amend current Section 2.4(g)(26) in Appendix A to Part 26, which requires the collector to complete the chain-of-custody forms for both the aliquot and the split sample and certify proper completion of the collection. The proposed rule would eliminate reference to the aliquot and split sample in the current paragraph to clarify the intent of this requirement, which is that the collector must complete the appropriate chain-of-custody forms for all of the sealed specimen and aliquot containers, not simply those resulting from a split specimen procedure. For example, if an FFD program follows split specimen procedures and conducts initial testing at a licensee testing facility, the donor's urine specimen may be divided into Bottle A, Bottle B, and another container that would be used for tests at the licensee testing facility. The proposed paragraph would retain the current requirement for the collector to certify proper completion of the collection.

Proposed §26.117(f) would amend current Section 2.4(g)(27) in Appendix A to Part 26, which states that the specimens and chain-of-custody forms are now ready for transfer and must be appropriately safeguarded if they are not immediately prepared for shipment. The proposed rule would replace the first sentence of the current provision, which states that the specimens and forms are ready for transfer, with a requirement for the collector to package the specimens and forms for transfer to the HHS-certified laboratory or licensee testing facility. This proposed change would improve the clarity in the rule's language, because it is necessary for the collector to package the specimens and chain-of-custody forms for transfer before they are ready to be transferred. The proposed paragraph would retain the second sentence of the current provision.

Proposed §26.117(g) would retain current Section 2.4(g)(28) in Appendix A to Part 26, which requires the collector to maintain control of the specimens and custody documents and ensure they are secure, if he or she must leave the workstation or collection site for any reason.

The proposed paragraph would make minor editorial changes to some of the terminology used in the current paragraph for consistency with the terminology used throughout the proposed rule, as discussed with respect to proposed §26.5 [Definitions], but retain the intended meaning of the current requirements.

Proposed §26.117(h) would retain the requirements in current Section 2.4(c)(2) in Appendix A to Part 26 related to maintaining specimen security until the specimens are sent to the licensee testing facility or the HHS-certified laboratory for testing from the collection site. The current paragraph would be moved to this section of the proposed rule for organizational clarity because this is the point in the specimen collection procedures at which requirements for maintaining specimen security would apply. The portion of the current paragraph that applies to situations in which it is impractical to maintain continuous physical security of a collection site would be moved to proposed §26.87(f)(5) for organizational clarity because proposed §26.87(f) addresses those circumstances.

Proposed §26.117(i) would update the specimen packaging requirements in current Section 2.4(i) in Appendix A to Part 26 by replacing the current paragraph with the related provision from the HHS Guidelines. The first sentence of the current paragraph, which directs collection site personnel to arrange to transfer the specimens to the licensee testing facility or HHS-certified laboratory, would be moved to proposed §26.117(j) for organizational clarity. Proposed §26.117(j) would address transfer and storage requirements, while proposed §26.117(i) would address packaging requirements. The proposed paragraph would also eliminate the initial phrases in the second sentence of the current paragraph, which list the conditions under which specimens will be transferred offsite (e.g., shipping specimens that test as “presumptive positive” on initial testing at the licensee testing facility, special processing of suspect specimens), because they would be redundant with other portions of the proposed rule.

Proposed requirements related to transferring specimens from a licensee testing facility to an HHS-certified laboratory for further testing would be moved to proposed §26.129(g) in Subpart F [Licensee Testing Facilities] for organizational clarity. The proposed rule would also eliminate the third sentence of the current paragraph, which requires the collector to sign and date the tape used to seal the container. This requirement would be eliminated because licensees and other entities now rely upon courier services to transfer specimens who offer other means of tracking the date that a container of specimens is shipped and the sender that program experience has shown are equally effective. The proposed paragraph would retain the intended meaning of the current requirements for the collector to place the specimens in a second container that minimizes the possibility of damage during shipment and seal them so that tampering will be detected. At the request of stakeholders during the public meetings discussed in Section V, the proposed rule would add shipping bags to the current set of examples of acceptable shipping containers that protect the specimens from damage. Also at the request of stakeholders, the proposed rule would delete the last sentence of the current paragraph, which requires the collector to ensure that chain-of-custody documents are attached to the container that is used to ship the specimens to the licensee testing facility or laboratory. The stakeholders requested this change because their practice is to seal the specimens' custody-and-control documentation inside the shipping container to ensure that it cannot be altered. The NRC endorses this practice as providing greater protection for donors and, therefore, proposes this change.

Proposed §26.117(j) would amend and combine the first sentence of current Section 2.4(i) in Appendix A to Part 26 with the requirements applicable to short-term storage of specimens at collection sites in current Section 2.7(c) in Appendix A to Part 26. The first sentence of current Section 2.4(i) in Appendix A to Part 26 would be moved to the proposed

paragraph for the reasons discussed with respect to proposed §26.117(i). Under the proposed paragraph, short-term refrigerated storage of specimens within 6 hours of collection would no longer be required for all specimens, as a result of advances in testing technologies. However, the proposed rule would continue to require licensees and other entities to protect specimens from any conditions that could cause specimen degradation. Collection site personnel would be required to refrigerate specimens that are not transferred or shipped to the licensee testing facility or the HHS-certified laboratory within 24 hours of collection. The proposed rule would also require that any specimens that may have been substituted or adulterated must be refrigerated as soon as they are collected, because some adulterants may interfere with drug testing results unless the specimen is refrigerated. The proposed rule would establish a time-limit of 2 business days for receipt of specimens at the licensee testing facility or HHS-certified laboratory, after shipment from the collection site, to further protect against potential specimen degradation.

Proposed §26.117(k) would amend the portions of current Section 2.4(h) in Appendix A to Part 26 that require every individual in the chain of custody to be identified on a specimen's custody-and-control form. The proposed rule would not require couriers to meet the requirements in current Section 2.4(h), which state that each time a specimen is handled or transferred, the date and purpose of the transfer must be documented on the chain-of-custody form and every individual in the chain of custody must be identified. Couriers would not be required to meet these requirements because custody-and-control forms for individual specimens would be packaged inside the shipping container where they are inaccessible to couriers so that it is impractical to expect them to sign them when handling the specimen shipping containers. The proposed paragraph would codify licensees' and other entities' current practices of relying upon courier services' normal package tracking systems to maintain

accountability for specimen shipping containers, which is consistent with the HHS Guidelines and standard forensic practices. The proposed rule would also eliminate the current requirement, contained in the last sentence of Section 2.4(h) in Appendix A to Part 26, to minimize the number of persons handling specimens because this requirement cannot be enforced.

Section 26.119 Determining “shy” bladder

A new §26.119 [Determining “shy” bladder] would be adapted from the DOT Procedures at 49 CFR 40.193 to specify procedures for determining whether a donor who does not provide a urine specimen of 30 mL within the 3 hours that would be permitted for a specimen collection is refusing to test or has a medical reason for being unable to provide the required 30 mL specimen. The proposed section would be respond to stakeholder requests during the public meetings discussed in Section V. The stakeholders reported that some donors have had difficulty providing the 60 mL of urine that was required in current Section 2.4(g)(11) for medical reasons, but the current rule does not establish procedures for handling such circumstances. As a result, some FFD programs have adopted the DOT “shy bladder” procedures, but the stakeholders preferred that the proposed rule incorporate the requirements to (1) clarify that the NRC accepts the procedures; (2) inform donors of the procedures that they are required to follow if they have medical reasons for being unable to provide a sufficient quantity of urine for testing; (3) enhance consistency among Part 26 programs; and (4) enhance the consistency of Part 26 procedures with the procedures that collectors must follow when conducting tests under DOT requirements. The NRC expects that fewer donors will be subject to “shy bladder” problems under the proposed rule because proposed §26.109 [Urine specimen quantity] would reduce the minimum quantity of urine required from 60 mL in the current rule to 30 mL.

However, because some donors' medical problems may also interfere with their ability to provide 30 mL of urine, the proposed rule would incorporate the DOT procedures. In general, the purpose of these proposed procedures is to protect the due process rights of individuals who are subject to Part 26. That is, the proposed section would establish procedures for ensuring that there is a legitimate medical reason that a donor was or is unable to provide a urine specimen of the required quantity so that the licensee or other entity has a medical basis for not imposing sanctions on the individual. In addition, the MRO would be authorized to devise alternative methods of drug testing, if it appears that the donor's medical problem would prevent him or her from being able to provide sufficient urine for drug testing in future tests.

Proposed §26.119(a) would be added to require that a licensed physician, who has appropriate expertise in the medical issues raised by the donor's failure to provide a sufficient specimen, must evaluate a donor who was unable to provide a urine specimen of at least 30 mL. The MRO would be permitted to perform the evaluation, if the MRO possesses the appropriate expertise. If not, the MRO would be required to review the qualifications of the physician and agree to the selection of that physician. These proposed requirements for the physician who performs the evaluation to be qualified in the relevant medical issues are necessary to ensure that the results of the evaluation would be valid.

The proposed paragraph would also require that the evaluation must be completed within 5 days of the unsuccessful collection. The 5-day time limit would be established on the basis of a trade-off between the necessity to provide the donor with sufficient time to locate a qualified physician, obtain an appointment, and for the physician to complete the evaluation (i.e., the donor's right to due process) and the public's interest in a rapid determination of whether the donor had attempted to subvert the testing process by refusing to provide a

sufficient specimen. The DOT's experience has indicated that 5 days is sufficient to complete the evaluation.

Proposed §26.119(b) would be added to specify the information that the MRO must provide to the physician who is selected to perform the evaluation if the MRO does not perform it. Proposed §26.119(b)(1) and (b)(2) would require the MRO to inform the physician that the donor was required to take a drug test under Part 26 but was unable to provide a sufficient quantity of urine for testing, and explain the potential consequences to the donor for a refusal to test. These proposed requirements would ensure that the evaluating physician understands the context in which he or she is being asked to perform the evaluation. Proposed §26.119(b)(3) would also require the MRO to inform the physician that he or she must agree to follow the procedures specified in proposed §26.119(c)–(f) if he or she performs the evaluation. This proposed requirement would ensure that the physician understands and consents to follow the proposed procedures specified in this section.

Proposed §26.119(c) would be added to describe the conclusions that the physician must provide to the MRO following the evaluation. Under proposed §26.119(c)(1), the physician may determine that a medical condition has, or with a high degree of probability could have, precluded the donor from providing the required quantity of urine. Or, under proposed §26.119(c)(2), the physician may determine that there is an inadequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the donor from providing a sufficient quantity of urine. The proposed rule would limit the physician's conclusions to one of these two alternatives in order to ensure that the results of the evaluation are relevant to and useful for determining whether sanctions must be imposed on the donor for a refusal to test.

Proposed §26.119(d) would be added to define the physical and psychological conditions that would constitute a medical condition that could have precluded the donor from providing a 30 mL specimen and provide examples of conditions that would not constitute a legitimate medical condition. Legitimate medical conditions would include an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder that precluded the donor from providing a 30 mL specimen. Unsupported assertions of "situational anxiety" or dehydration would be examples of conditions that could not be considered legitimate medical conditions. The proposed rule would add this paragraph to provide necessary guidance to the evaluating physician.

Proposed §26.119(e) would be added to require the evaluating physician to provide a written statement of his or her findings and conclusion from the evaluation. By implication, if the MRO performs the evaluation, the MRO would provide this written statement. The written statement would be necessary to communicate the results of the evaluation and create a record of it, should any question arise later with respect to the determination.

The proposed paragraph would also require that the physician must provide only the information that is necessary to support the physician's conclusion. This proposed requirement would be added to protect the donor's privacy by ensuring that the only medical information documented is information that is necessary to support the determination.

Proposed §26.119(f) would be added to require the physician to inform the MRO, in the written statement, whether any medical condition that may be identified would also preclude the donor from providing specimens of 30 mL or more in future collections. This information would be necessary for the MRO to determine whether alternative methods of drug testing must be implemented for the donor, as required under proposed §26.119(g)(3).

Proposed §26.119(g) would be added to prescribe the actions to be taken by the MRO based on the results of the evaluation, as follows:

Proposed §26.119(g)(1) would require the MRO to determine that the donor did not violate the FFD policy, if the physician concluded that a medical condition could account for the insufficient specimen and the MRO concurred with that conclusion. In this instance, the licensee or other entity would not impose sanctions on the donor because the donor had not violated the FFD policy by refusing to test.

Proposed §26.119(g)(2) would require the MRO to determine that the donor had refused to be tested by failing to provide a sufficient specimen, if the physician concluded that a medical condition could not account for the insufficient specimen. In this instance, the licensee or other entity would impose the sanction of a permanent denial of authorization for an attempt to subvert the testing process, as required under proposed §26.75(b).

Proposed §26.119(g)(3) would require the MRO to devise an alternative method of collecting specimens for drug testing, if the donor's medical condition would, over the long-term, consistently prevent the donor from providing urine specimens of 30 mL or more. For example, the proposed provision would permit the MRO to direct the collection and testing of alternate specimens, including, but not limited to, hair, or other bodily fluids, if, in the MRO's professional judgment, the collection and analysis of these alternate specimens would be scientifically defensible and forensically sound. The proposed paragraph would grant flexibility to the MRO in exercising his or her professional judgment in determining an alternative method of conducting drug testing, rather than establish detailed requirements which may not appropriately address the range of possible medical conditions that could arise.

Subpart F – Licensee Testing Facilities

Section 26.121 Purpose

A new §26.121 [Purpose] would be added to provide an overview of the contents of the proposed subpart, consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Section 26.123 Testing facility capabilities

Proposed §26.123 [Testing facility capabilities] would amend the second sentence of current Section 2.7(l)(2) in Appendix A to Part 26 as it relates to the capabilities of licensee testing facilities. The proposed paragraph would retain the current requirement for licensee testing facilities to be capable of performing initial tests for each drug and drug metabolite for which testing is conducted by the FFD program and would add a requirement for licensee testing facilities to have the capability to perform either validity screening tests, initial validity tests, or both. The first sentence of current Section 2.7(l)(2), which establishes requirements for the capabilities of HHS-certified laboratories would be moved to proposed Subpart G [Laboratories Certified by the Department of Health and Human Services]. The last sentence of the current paragraph, which permits the testing of breath specimens for alcohol at the collection site, would be deleted here because the proposed rule would address alcohol testing in Subpart E [Collecting Specimens for Testing]. These proposed organizational changes to the current paragraph would be made to meet Goal 6 of this rulemaking, which is to improve organizational clarity in the rule.

Section 26.125 Licensee testing facility personnel

Proposed §26.125 [Licensee testing facility personnel] would amend current Section 2.6 in Appendix A to Part 26, as follows:

Proposed §26.125(a) would retain current Section 2.6(a) in Appendix A to Part 26, which requires each licensee testing facility to have one or more individuals who are responsible for the day-to-day operations of the facility and establishes requirements for those individuals' qualifications. The proposed paragraph would make minor changes in the language of this paragraph, which would be consistent with amended language in the related portion of the HHS Guidelines.

Proposed §26.125(b) would amend current Section 2.6(b) in Appendix A to Part 26, which requires laboratory technicians and nontechnical staff to have the necessary training and skills for the tasks assigned to them. The proposed rule would retain the first sentence of the current provision, but would add another. The proposed rule would require laboratory technicians who perform urine specimen testing to demonstrate proficiency in operating the testing instruments and devices used at the licensee testing facility. This proficiency requirement would be added to ensure that technicians are capable of correctly using the instruments and devices that the licensee testing facility has selected for validity and drug testing. This proposed change is necessary for several reasons. First, the proposed rule would add new requirements for licensee testing facilities to conduct validity testing, and the instruments and devices that the technicians would be using are likely to differ from those previously used at licensee testing facilities. Therefore, additional training and proficiency testing would be required to ensure that validity testing would be conducted properly. Second, proposed rule permits licensees and other entities to rely on drug test results from testing that was performed by another Part 26 program to a greater extent than the current rule. Therefore,

it is necessary to ensure that all drug testing performed under Part 26, including tests performed at licensee testing facilities, meets minimum standards. The proposed requirement for technicians to demonstrate proficiency, then, would contribute to meeting this goal. Third, the experience of other Federal agencies has shown that requirements for technicians to demonstrate proficiency assist in any litigation that may occur with respect to urine test results.

Proposed §26.125(c) would amend current Section 2.6(c) in Appendix A to Part 26, which establishes recordkeeping requirements for the personnel files of licensee testing facility personnel. The current requirement for records of tests for color blindness would be eliminated here, consistent with a similar change to the HHS Guidelines. Tests for color blindness would no longer be necessary because current testing technologies provide means other than color for reading test results.

Section 26.127 Procedures

Proposed §26.127 [Procedures] would combine, reorganize, and amend requirements for procedures that are interspersed throughout Appendix A to Part 26, including requirements in current Sections 2.2 and 2.7. These organizational changes would be made to improve clarity in the organization of the rule by grouping procedural requirements for licensee testing facilities in one section.

Proposed §26.127(a) would make minor editorial changes to the first sentence of current Section 2.2 in Appendix A to Part 26, which requires licensee testing facilities and HHS-certified laboratories to have detailed procedures for conducting testing. The proposed rule would delete the current reference to blood samples because donors would no longer have the option to request blood testing for alcohol, as discussed with respect to proposed §26.83(a). Reference to HHS-certified laboratories would be moved to proposed §26.157(a) in Subpart G

[Laboratories Certified by the Department of Health and Human Services] to improve the organizational clarity of the rule. The proposed rule would also delete the current reference to procedures for specimen collections, because procedural requirements for specimen collections would be relocated to proposed Subpart E [Collecting Specimens for Testing].

Proposed §26.127(b) would combine and amend portions of the requirements in the first sentence of current Sections 2.4(d) and 2.7(a)(2) in Appendix A to Part 26 related to the content and implementation of specimen chain-of-custody procedures. The proposed paragraph would retain the portions of the current paragraphs that require licensee testing facilities to develop, implement, and maintain written chain-of-custody procedures to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to the HHS-certified laboratory, and continuing until final disposition of the specimens. The current requirements related to HHS-certified laboratories would be moved to proposed §26.157(b) in Subpart G [Laboratories Certified by the Department of Health and Human Services] to improve organizational clarity. The proposed rule would also remove references to custody-and-control procedures for blood specimens because donors would no longer have the option to request blood testing for alcohol, as discussed with respect to proposed §26.83(a).

Proposed §26.127(c) would retain the portions of current Section 2.7(o)(1) in Appendix A to Part 26 that address the required content of procedures for licensee testing facilities and amend the current requirements. The proposed paragraph would retain the portions of the current provision that require licensee testing facilities to develop and maintain procedures to specify all of the elements of the testing process, including, but not limited to, the principles of each test and the preparation of reagents, standards, and controls. The proposed paragraph would present the required topics of the procedures in a list format in proposed

§26.127(c)(1)–(c)(12) to clarify that each topic stands on its own, and to improve clarity in the organization of the rule.

Proposed §26.127(c) would also amend current Section 2.7(o)(1) in Appendix A to Part 26 in several ways. First, the proposed paragraph would eliminate the current requirement for the procedures to be maintained in a laboratory manual as unnecessarily restrictive. Licensee testing facilities would be permitted to use other means to maintain their procedures. Second, the proposed paragraph would add a requirement for the development, implementation, and maintenance of written standard operating procedures for validity testing instruments and devices, consistent with the addition of requirements to conduct validity testing throughout the proposed rule. Third, two portions of the current provision would be moved to other subparts of the proposed rule that address related topics to improve clarity in the organization and language of the rule, as follows: The last two sentences of current Section 2.7(o)(1) in Appendix A to Part 26, which address requirements for retaining copies of superceded procedures, would be relocated to §26.215(a) of Subpart J [Recordkeeping and Reporting Requirements] of the proposed rule. Procedural requirements for HHS-certified laboratories would be moved to §26.157(b) in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services].

Proposed §26.127(d) would amend current Section 2.7(o)(3)(iii) in Appendix A to Part 26, which requires procedures for the setup and normal operation of testing instruments, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. The proposed paragraph would extend the current requirements to non-instrumented devices (such as some validity screening devices), if the licensee testing facility uses such devices, consistent with the addition of requirements to conduct validity testing throughout the proposed rule. The

proposed rule would also make three organizational changes to the current provision. The proposed paragraph would present the required topics of the procedures in a list format in proposed §26.127(d)(1)–(d)(3) to clarify that each topic stands on its own. The current requirement to maintain records of preventative maintenance would be relocated to §26.215(b)(10) in Subpart J [Recordkeeping and Reporting Requirements] of the proposed rule. And, the current requirements that apply to HHS-certified laboratories would be moved to §26.157(d) in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services]. These proposed changes would made to improve clarity in the organization of the rule.

Proposed §26.127(e) would reorganize and amend current Section 2.7(o)(4) in Appendix A to Part 26, which requires documented corrective actions if systems are out of acceptable limits or errors are detected. The proposed paragraph would extend the current requirement to non-instrumented validity screening devices, if the licensee testing facility uses such devices, consistent with the addition of requirements to conduct validity testing throughout the proposed rule. The requirements in the current paragraph that apply to HHS-certified laboratories would be moved to §26.157(e) in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity.

Section 26.129 Assuring specimen security, chain of custody, and preservation

Proposed §26.129 [Assuring specimen security, chain of custody, and preservation] would be added to group together in one section the requirements of the proposed rule that apply to licensee testing facilities with respect to the safeguarding of specimen identity, integrity, and security. This proposed organizational change would be made because requirements that address these topics are dispersed throughout the current rule whereas

grouping them together in a single section would make them easier to locate within the proposed rule.

Proposed §26.129(a) would retain the first four sentences of current Section 2.7(a)(1) in Appendix A to Part 26, which require licensee testing facilities to be secure and accessible only to authorized personnel. These requirements as they apply to HHS-certified laboratories would be moved to proposed §26.159(a). The last sentence of the current paragraph, which establishes recordkeeping requirements, would be moved to §26.215(b)(13) in proposed Subpart J [Recordkeeping and Reporting Requirements]. The proposed changes would be made for organizational clarity.

Proposed §26.129(b) would amend current Section 2.7(b)(1) in Appendix A to Part 26, which establishes requirements for receiving specimens at the licensee testing facility and assuring their integrity and identity. The proposed rule would move the current requirements related to HHS-certified laboratories to §26.159(b) in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity. Several requirements would also be added to the proposed paragraph, as follows:

The proposed paragraph would add requirements for licensee or other entity management personnel to investigate any indications of specimen tampering and take corrective actions if tampering is confirmed. The proposed rule would add these requirements because some licensees have not investigated or taken corrective actions in response to indications of tampering with specimens under the current rule. The appropriate corrective actions that management personnel would take would depend upon the nature of the tampering identified as a result of the investigation. For example, if the investigation indicated that the tampering was an attempt to subvert the testing process and the persons involved were identified, management personnel would impose the sanctions in proposed §26.75(b) for a

subversion attempt. Management personnel would also be required to correct any systematic weaknesses in specimen custody-and-control procedures that may be identified in the investigation, such as inadequate safeguarding of specimen shipping containers.

The proposed paragraph would also add a requirement for licensee testing facility personnel to attempt to resolve any discrepancies in the information on specimen bottles or on the accompanying custody-and-control forms to ensure the identity and integrity of specimens and prevent specimens from being unnecessarily rejected for testing by the HHS-certified laboratory (if the specimen must be subject to additional testing) when flaws can be corrected. For example, if the collector's signature is missing on the custody-and-control form, licensee testing facility personnel would work with collection site personnel to attempt to identify the collector and obtain the collector's signature on the form if possible. This proposed requirement would reduce the potential burden on donors who may otherwise be required to submit additional specimens to replace those for which the chain-of-custody could not be confirmed. The proposed requirements would also improve the efficiency of FFD programs by avoiding the need to conduct additional specimen collections when discrepancies can be corrected. The proposed provision would also meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The proposed paragraph would also add a prohibition on testing of any specimens if the licensee or other entity has reason to believe that the specimens that were subject to tampering had been altered in such a manner as to affect specimen identity and integrity. In these circumstances, the MRO would cancel testing of the specimens or any test results from those specimens, and require the licensee or other entity to retest the donors who had submitted them. Although the NRC is not aware of any instances in which these circumstances have arisen in Part 26 programs, the experience of other Federal agencies indicates such tampering

is possible. Therefore, this requirement would be necessary to ensure that individuals are not subject to sanctions for a non-negative test result from a specimen that may not have been theirs. The proposed change would be made to meet Goal 7 of this rulemaking, which is to protect the due process rights of individuals who are subject to Part 26. The additional provision would also be consistent with the requirements of other Federal agencies.

Proposed §26.129(c) would amend current Section 2.7(b)(2) in Appendix A to Part 26, which establishes requirements for chain-of-custody procedures for specimens and aliquots at licensee testing facilities. The proposed rule would move the requirements in the current paragraph that are related to HHS-certified laboratories to proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] to improve organizational clarity. In addition, the proposed paragraph would add a reference to specimen validity testing for consistency with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

The proposed paragraph would incorporate two additional changes to the current provision at the request of stakeholders at the public meetings discussed in Section V. The stakeholders requested that the proposed rule permit licensee testing facilities to use methods other than a custody-and-control form to maintain the chain of custody for aliquots of a specimen that are tested at the licensee testing facility. The proposed change would be incorporated because methods other than a custody-and-control form, such as the use of bar coding, have been shown to be equally effective at tracking the chain of custody for an aliquot at licensee testing facilities. Continuing to permit such flexibility would be consistent with Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

The stakeholders also requested that the proposed paragraph specify the conditions under which specimens and aliquots may be discarded because the current rule does not address discarding of negative specimens. Therefore, the proposed rule would permit licensee testing facilities to discard specimens and aliquots as soon as practical after validity screening or initial validity tests have demonstrated that the specimen appears to be valid and initial test results for drugs and drug metabolites are negative. The proposed clarification would codify current licensee practices. This permission would have no impact on donors' rights under the rule, because donors are not at risk of management actions or sanctions as a result of negative test results and, therefore, would not need the licensee testing facility to retain the specimen for additional testing for review or litigation purposes. The proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

Proposed §26.129(d) would update current Section 2.7(a)(2) in Appendix A to Part 26, which requires licensee testing facility personnel to maintain and document the chain of custody for specimens and aliquots. The proposed paragraph would incorporate the simpler language of the related provision from the HHS Guidelines while retaining the intent of the current paragraph. The proposed rule would relocate the requirements in the current paragraph that are related to HHS-certified laboratories to §26.159(d) and (e) in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] to improve organizational clarity.

Proposed §26.129(e) would amend the first sentence of current Section 2.7(d) in Appendix A to Part 26, which requires specimens that test as "presumptive positive" at the licensee testing facility to be shipped to the HHS-certified laboratory for further testing. The proposed rule would replace the term, "presumptive positive," with the term, "non-negative," in order to address validity testing results, consistent with the addition of requirements to conduct

validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). For organizational clarity, the requirements in current Section 2.7(d) in Appendix A to Part 26 that relate to quality control procedures for testing at licensee testing facilities and HHS-certified laboratories would be moved to proposed §§26.137 [Quality assurance and quality control] and 26.167 [Quality assurance and quality control], respectively.

Proposed §26.129(f) would clarify and revise current Section 2.7(c) in Appendix A to Part 26, as it relates to refrigerating urine specimens to protect them from degradation. For organizational clarity, the proposed rule would move the current requirements that apply to HHS-certified laboratories to proposed §26.159(h) in Subpart G [Laboratories Certified by the Department of Health and Human Services]. The proposed paragraph would restate portions of the current provision and add a performance standard regarding "appropriate and prudent actions" to minimize specimen degradation. For the reasons discussed with respect to proposed §26.117(j), the proposed rule would no longer require all specimens to be refrigerated within 6 hours after collection, but would add a requirement that any specimen that has not been tested within 24 hours of receipt at the licensee testing facility must be refrigerated. The proposed paragraph would continue to require the licensee or other entity to refrigerate any specimen (and the associated Bottle B for that specimen, if the FFD program follows split specimen procedures) that yields non-negative results from initial drug testing at the licensee testing facility. The proposed rule would also add a requirement for refrigerating any specimen (and the associated Bottle B) that yields non-negative results from validity screening or initial validity testing at the licensee testing facility. Refrigerating these specimens would be necessary because some adulterants have been shown to interfere with drug test results more rapidly if the specimen remains at room temperature.

The proposed rule would eliminate as unnecessary the last sentence of the current paragraph, which requires licensee testing facilities to ensure that emergency power equipment is available to maintain the specimens cooled in the event of a power failure. With improvements in the courier services available to licensee testing facilities since Part 26 was first published, licensee testing facilities are typically able to ship specimens to the HHS-certified laboratory on the same day that specimens are tested. Further, program experience since the rule was implemented indicates that the periods of time that licensee testing facilities are without off-site power are typically limited to a few hours at most, which would not be long enough for specimen degradation to occur. Therefore, the proposed change would be made to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

The proposed rule would also update the terminology used in the current paragraph to be consistent with the new terminology adopted throughout the proposed rule for referring to split specimens. Therefore, in the proposed paragraph, the licensee testing facility would continue to be responsible for protecting from degradation the primary specimen (Bottle A) and the specimen in Bottle B of a split specimen, if the FFD program follows split specimen procedures. The licensee testing facility would also be required to refrigerate any specimen that yields non-negative test results, Bottle B of any specimen in Bottle A that tests as non-negative, and any specimen that is not tested within 24 hours of receipt at the licensee testing facility. These changes in the terminology of the proposed paragraph would be made to improve clarity in the language of the proposed rule.

Proposed §26.129(g) and (h) would separate current Section 2.4(i) in Appendix A to Part 26 into two paragraphs for organizational clarity and amend the current provision for the reasons previously discussed with respect to proposed §26.117(i) and (k). Proposed

§26.129(g) and (h), which repeat the requirements for packaging and shipping specimens contained in proposed §26.117(i) and (k) of Subpart E [Collecting specimens for testing], would apply these requirements to packaging and shipping specimens from licensee testing facilities to HHS-certified laboratories. The bases for these requirements are discussed with respect to proposed §§26.117(i) and (k).

Section 26.131 Cutoff levels for validity screening and initial validity tests

A new §26.131 [Cutoff levels for validity screening and initial validity tests] would be added to establish cutoff levels for validity screening and initial validity tests at licensee testing facilities for creatinine, pH, and oxidizing adulterants. The procedures, substances, and cutoff levels for initial validity testing in the proposed section would incorporate the related requirements from the HHS Guidelines (69 FR 19643; April 13, 2004). The proposed validity screening test requirements would be adapted from the HHS proposed revision to the Guidelines that was also published in the Federal Register on April 13, 2004 (69 FR 19673).

By contrast to the requirements for initial validity testing in the HHS Guidelines, the proposed rule would not require licensee testing facilities to evaluate the specific gravity of a specimen that has a creatinine concentration of less than 20 milligrams (mg) per deciliter (dL). Specimens with a low creatinine concentration may be dilute or substituted. Instead, if the specimen's creatinine concentration is less than 20 mg/dL, the proposed rule would require the licensee testing facility to forward the specimen to the HHS-certified laboratory to complete the testing, where the specimen's specific gravity would be measured. The proposed rule would differ from the HHS Guidelines in this provision because the costs of the instruments (i.e., refractometers) that are required in the Guidelines for measuring specific gravity are high. Some licensee testing facilities are currently measuring the specific gravity of specimens.

However, the cutoff levels established in the Guidelines require more sensitive measurement and licensee testing facilities would be required to purchase new equipment in order to test at the new HHS specific gravity cutoff levels. Therefore, the proposed rule would require licensee testing facilities to ship specimens with low creatinine concentrations to the HHS-laboratory to complete the initial testing process and would not include cutoff levels for specific gravity or quality control requirements for measuring specific gravity in this proposed subpart. The NRC invites comment on this issue.

Proposed §26.131(a) would be added to require licensee testing facilities to perform either validity screening tests, initial validity tests, or both. Consistent with related requirements for further testing of specimens that yield drug-positive results from initial testing at a licensee testing facility, the proposed rule would also require licensee testing facilities to forward specimens that yield non-negative validity testing results to an HHS-certified laboratory for further testing. Further testing at an HHS-certified laboratory is necessary because licensee testing facilities do not have the sophisticated testing instruments for conducting confirmatory testing that are required under the HHS Guidelines. In addition, further testing at an HHS-certified laboratory provides an independent check on test results from licensee testing facilities that is necessary to protect donors' rights to due process under Part 26, consistent with Goal 7 of this rulemaking.

As discussed in Section IV. C, the primary distinction between validity screening tests and initial validity tests is that validity screening tests may be performed using non-instrumented devices, such as dipsticks, whereas initial validity tests generally rely upon more complex testing technologies. The proposed rule would permit licensee testing facilities to perform validity screening tests before performing initial validity tests, but would not require them to do

so, because validity screening tests would be unnecessary if the licensee testing facility will perform initial validity testing.

Proposed §26.131(b) would be added to require licensee testing facilities to test each urine specimen for its creatinine concentration, pH, and the presence of one or more oxidizing adulterants, such as nitrite or bleach. Abnormal creatinine concentrations and pH values, and the presence of oxidizing adulterants are indicators that a specimen has been adulterated or substituted. The proposed rule would permit the FFD program to choose the oxidizing adulterant(s) for which testing would be conducted. The requirements in this proposed paragraph would be consistent with the related requirements in the current HHS Guidelines.

Proposed §26.131(b) would also establish the criteria for determining whether a specimen must be forwarded to the HHS-certified laboratory for further validity testing. The proposed criteria would be incorporated from the current HHS Guidelines. Because validity testing is complex and the methods for testing are relatively new, the proposed rule would not permit an FFD program to establish more stringent cutoff levels for validity screening and initial validity testing. This proposed prohibition is necessary to decrease the risk of obtaining false non-negative test results and would ensure that donors are not subject to sanctions on the basis of inaccurate test results.

Section 26.133 Cutoff levels for drugs and drug metabolites

A new §26.133 [Cutoff levels for drugs and drug metabolites] would amend current Section 2.7(e)(1) in Appendix A to Part 26, which establishes cutoff levels for initial testing for drugs and drug metabolites. Proposed §26.133 would replace and amend some cutoff levels for initial tests for drugs and drug metabolites in current Section 2.7(e)(1) in Appendix A to Part 26 to be consistent with the HHS cutoff levels for the same substances.

The initial test cutoff level for marijuana metabolites would be decreased from 100 nanograms (ng) per milliliter (mL) to 50 ng/mL. Current immunoassay techniques can now reliably detect the presence of marijuana metabolites at this cutoff level. As discussed in Section IV. B, this proposed change would strengthen the effectiveness of FFD programs by increasing the likelihood of detecting marijuana use.

The proposed rule would increase the initial test cutoff level for opiate metabolites from 300 ng/mL in the current rule to 2,000 ng/mL. The proposed change in the cutoff level for opiate metabolites would substantially reduce the number of positive opiate test results that are reported to MROs by HHS-certified laboratories that MROs ultimately verify as negative.

The proposed rule would continue to permit licensees and other entities to establish more stringent cutoff levels for initial drug tests, subject to the requirements specified in proposed §26.31(d)(3)(iii), for the reasons discussed with respect to that paragraph.

The current requirement for licensees and other entities to report drug test results for both the cutoff levels in the rule and more stringent cutoff levels would be eliminated in the proposed rule. The reason that the current rule requires FFD programs to report test results for the cutoff levels specified in this part, when the licensee is using more stringent cutoff levels, is that it provides means for the NRC to monitor licensees' implementation of the permission to use more stringent cutoff levels. The proposed rule would eliminate this requirement, because proposed §26.31(d)(3)(iii)(C) would require a qualified forensic toxicologist to certify the scientific and technical validity of the licensee's or other entity's testing process at any lower cutoff levels. Therefore, the reporting requirement would no longer be needed to assure licensee testing facility performance in this area. Eliminating this requirement would meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.135 Split specimens

A new §26.135 [Split specimens] would reorganize and amend the requirements contained in current Section 2.7(j) in Appendix A to Part 26 that relate to licensee testing facility handling of split specimens. The proposed requirements would apply only if the FFD program follows split specimen procedures. The current paragraph would be divided into separate paragraphs in the proposed section to indicate that each requirement stands on its own. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.135(a) would amend the second, third, and fourth sentences of current Section 2.7(j) in Appendix A to Part 26. The proposed rule would revise the terminology used in these sentences (e.g., “Bottle A” rather than “primary specimen,” “Bottle B” rather than “split specimen,” “non-negative” rather than “presumptive positive”) to be consistent with terminology used in other parts of the proposed regulation without amending the meaning of the sentences. The requirement in the third sentence of current Section 2.7(j) to seal the split specimen prior to placing it in secure storage would be deleted in the proposed rule, because Bottles A and B would have already been sealed at the collection site, as required in proposed §26.113(b)(3). The proposed paragraph would add a requirement to forward Bottle A of the split specimen to the HHS-certified laboratory, in the case of any non-negative validity test results at the licensee testing facility. This proposed requirement would be consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.135(b) would amend the requirements in current Section 2.7(j) in Appendix A to Part 26 related to donor requests for testing of the specimen in Bottle B. The proposed paragraph would add non-negative validity test results as a basis for a donor request

for testing the specimen in Bottle B consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The proposed paragraph would also add a requirement that the donor must request testing of the Bottle B specimen within 3 business days of being notified by the MRO that the specimen in Bottle A has yielded confirmed non-negative test results. Since 1994, the HHS Guidelines have allowed up to 72 hours for a donor to make this request, so the proposed change would increase the consistency of Part 26 with the HHS Guidelines to meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The proposed paragraph would also eliminate the requirement in the fourth sentence of current Section 2.7(j) in Appendix A to Part 26, which requires that the split specimen must be forwarded to another HHS-certified laboratory for testing on the same day of the donor request. Licensees and other entities would be permitted up to one business day to forward Bottle B to a second HHS-certified laboratory following the donor request. This proposed change would respond to stakeholder feedback provided during the public meetings discussed in Section V. The stakeholders reported that implementing the same-day requirement has often been difficult for a number of reasons, including, for example, communication delays among donors, MROs, and FFD program personnel, particularly on weekends and holidays, and the time required to identify a second laboratory with the appropriate capability to test the split specimen, depending upon the nature of the non-negative test result. The proposed rule would alleviate some of these types of logistical difficulties (e.g., logistical problems associated with weekends and holidays) while continuing to provide the donor with timely test results. Therefore, this proposed change would be made to meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

The proposed paragraph would also require the donor to provide written permission to the licensee or other entity for testing of the specimen contained in Bottle B and clarify that only the donor may authorize testing of Bottle B. Stakeholders have indicated that the requirement for a written request from donors would impose a substantial logistical burden for donors who may not be working on site when contacted by the MRO. However, the NRC believes that the proposed requirement is necessary to ensure that the donor's right to privacy and control of the specimen would be protected, consistent with Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Proposed §26.135(c) would update the terminology used in the portions of current Section 2.7(h) in Appendix A to Part 26 that apply to storing specimens at licensee testing facilities. For example, the proposed provision would replace the term, "split specimen," with the term, "Bottle B." The proposed paragraph would continue to require licensee testing facilities who retain Bottle B of a confirmed non-negative split specimen to store it in long-term frozen storage for at least one year before discarding it, or longer if the specimen is under legal challenge, or at the request of the NRC. The proposed rule would extend the current requirement to apply to Bottle B of any specimen that has yielded non-negative validity test results, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The portions of current Section 2.7(h) in Appendix A to Part 26 that apply to HHS-certified laboratories would be moved to §26.159(i) in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] to improve the organizational clarity of the rule.

Section 26.137 Quality assurance and quality control

A new §26.137 [Quality assurance and quality control] would amend current Section 2.8 in Appendix A to Part 26. The proposed section would add quality control requirements for performing validity screening tests, initial validity tests, and initial tests for drugs and drug metabolites at the licensee testing facility, for the reasons to be discussed with respect to each proposed paragraph. The portions of current Section 2.8 in Appendix A to Part 26 that establish requirements for HHS-certified laboratories would be moved to §26.167 in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity.

Proposed §26.137(a) [Quality assurance program] would amend current Section 2.8(a) in Appendix A to Part 26, which requires licensee testing facilities and HHS-certified laboratories to have a quality assurance program for all aspects of the testing process. The requirements for HHS-certified laboratories would be moved to §26.167(a) in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] to improve organizational clarity. The proposed paragraph would extend the current requirements for licensee testing facilities to have a quality assurance program and procedures to validity testing at the licensee testing facility, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.137(b) [Performance testing and quality control requirements for validity screening tests] would be added to establish requirements for conducting validity screening tests for the reasons discussed with respect to proposed §26.31(d)(3)(i). The proposed requirements in this paragraph are based upon requirements that have been proposed by HHS in a Notice of Proposed Revisions to the Mandatory Guidelines dated April 13, 2004 (69 FR 19673).

Proposed §26.137(b)(1) would permit licensee testing facilities to use non-instrumented devices, such as dipsticks, to determine whether a specimen appears to be valid or must be subject to further validity testing. However, in proposed §26.137(b)(1)(i) and (ii), licensee testing facilities would be permitted to use only non-instrumented devices that either have been cleared by the U.S. Food and Drug Administration and placed on the SAMHSA list of point-of-collection testing devices that are certified for use in the Federal Workplace Drug Testing Program, as published in the Federal Register, or that meet the performance testing criteria set forth in proposed §26.137(b)(1)(ii). SAMHSA has yet to publish a list of certified devices, but, in order to be added to SAMHSA's list, SAMHSA will require that a device must meet the performance testing requirements that are contained in proposed §26.137(b)(1)(ii). Therefore, adding these requirements to the proposed rule would permit licensee testing facilities to conduct the required performance testing and begin using any devices that meet the criteria before SAMHSA's list is published.

The NRC is aware that the performance testing requirements in proposed §26.137(b)(1)(ii) are stringent and that few, if any, validity screening devices are yet available that meet them. However, because individuals may be subject to a temporary administrative withdrawal of authorization on the basis of a non-negative initial drug test result for marijuana or cocaine from a specimen that appears to be valid [see proposed §26.75(i)], it is critical that any validity screening devices used in Part 26 programs provide accurate results. The proposed performance testing requirements would be necessary to protect donors from inaccurate results, as well as ensure that specimens of questionable validity would be detected.

Proposed §26.137(b)(1)(iii) and (b)(1)(iv) would require licensee testing facilities to ensure that any validity screening devices placed into service continue to be effective in determining the validity of urine specimens. Proposed §26.137(b)(1)(iii) would require licensee

testing facilities to ensure that the device(s) either remains on the SAMHSA list of certified devices (when it becomes available) or continues to meet the performance testing criteria in proposed §26.137(b)(1)(ii)(A)–(b)(1)(ii)(C) by conducting further performance testing on a nominal yearly schedule. The proposed requirement would be consistent with the related requirement in HHS's proposed revisions to the Guidelines. Proposed §26.137(b)(1)(iv) would require licensee testing facilities to ensure that the manufacturer of any validity screening device used informs the licensee or other entity of modifications to the device, so that the licensee or other entity may determine whether additional performance testing is required to demonstrate that the modified device continues to be effective. These proposed provisions would be necessary to protect donors from inaccurate results, as well as provide assurance that specimens of questionable validity are detected.

Proposed §26.137(b)(2) would require licensee testing facility personnel to use the validity screening device to test quality control samples at the beginning of any 8-hour period during which validity screening tests will be performed. The proposed rule would require the quality control samples to consist of one sample that is certified as negative and one that is non-negative for the specific validity test for which the device is designed. For example, if the device tests for nitrite, licensee testing facility personnel would use a certified quality control sample containing nitrite. If the device fails to perform correctly when testing the quality control samples, the proposed rule would require the licensee testing facility to stop using it immediately and initiate the investigation required in proposed §26.137(f). If the test result is a false negative, the last sentence of the proposed paragraph would require the licensee or other entity to notify the NRC. The proposed rule would not require notifying the NRC of a false positive result because any specimen that yields a non-negative validity screening test result would be forwarded to the HHS-certified laboratory for further testing, and licensees and other

entities would be prohibited from taking any management actions until the HHS-certified laboratory completes testing of the specimen and the MRO has reviewed the results. Therefore, false positive test results from the device would not impose a burden on donors. These proposed procedures are necessary to protect donors from inaccurate test results, as well as to provide assurance that specimens of questionable validity are detected.

Proposed §26.137(b)(3) would require licensee testing facility personnel to submit 1 out of every 10 donor specimens that yield negative results using the device to the HHS-certified laboratory. If the HHS-certified laboratory's results indicate that the device had provided a false negative result, the proposed rule would require the licensee testing facility to stop using the device immediately, initiate the investigation required in proposed §26.137(f), and notify the NRC.

The NRC notifications that would be required in proposed §26.137(a) and (b) would be necessary because false negative results from a validity screening device could mean that some attempts to subvert the testing process may not be detected. For example, if an individual had adulterated his or her specimen and it was not detected because of a faulty device, the licensee or other entity would have no reason to terminate the individual's authorization. As a result, the individual, who has demonstrated that he or she is not trustworthy and reliable, would be permitted to perform job duties under this part and pose a risk to public health and safety and the common defense and security. The NRC would use the information to ensure that HHS is notified of the device failure as well as inform other licensees and entities who may also be using the device of the false negative results to prevent additional testing errors. Therefore, the proposed notifications would be necessary to protect donors from inaccurate test results, to ensure that specimens of questionable validity are detected, and to ensure that any problems with a device are detected and corrected as soon as possible.

Proposed §26.137(b)(4) would require that any non-instrumented validity screening device used by a licensee testing facility must be capable of measuring creatinine to 1 decimal place. This proposed requirement would be necessary to ensure that the device can support the creatinine cutoff levels established in the HHS Guidelines, as incorporated into the proposed rule.

Proposed §26.137(b)(5) and (b)(6) would establish quality control requirements for performing validity screening tests for pH and oxidizing adulterants, respectively. These proposed requirements would incorporate the related requirements in the proposed HHS Guidelines.

Proposed §26.137(c) [Non-negative validity screening test results] would be added to specify the actions that the licensee testing facility must take if the results of validity screening tests are non-negative. If validity screening test results are non-negative, the proposed rule would require instrumented initial validity testing either at the licensee testing facility or the HHS-certified laboratory. This proposed provision would be consistent with current requirements for handling specimens that test as drug-positive on initial tests at a licensee testing facility. The proposed requirement would be necessary to protect donors from inaccurate test results, as well as provide assurance that specimens of questionable validity are detected using the more sophisticated technologies required for instrumented initial validity testing in the HHS Guidelines and the proposed rule.

Proposed §26.137(d) [Quality control requirements for performing initial validity tests] would be added to specify the required methods for performing initial validity tests at a licensee testing facility to ensure that initial validity testing at the licensee testing facility would provide accurate results. The proposed requirements in this paragraph would incorporate the related requirements in the HHS Guidelines as revised on April 13, 2004 (69 FR 19644). The proposed

paragraph would be added to meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.137(d)(1) would require licensee testing facilities to measure creatinine concentration to 1 decimal place and would establish requirements for the controls to be used in initial tests for creatinine concentration.

Proposed §26.137(d)(2) would establish quality control requirements for performing initial pH tests. Proposed §26.137(b)(2)(i)–(b)(2)(v) would specify the required calibrators and controls for initial pH testing, based upon the type of testing instrument used and whether a pH validity screening test has been performed.

Proposed §26.137(d)(3) would establish quality control requirements for performing initial tests for oxidizing adulterants, including nitrite, and proposed §26.137(d)(4) would establish quality control requirements for performing initial tests for “other” adulterants at the licensee testing facility.

Proposed §26.137(e) [Quality control requirements for initial drug tests] would amend and combine portions of current Sections 2.7(d), 2.7(e)(1), and 2.8(b) in Appendix A to Part 26, which establish quality control requirements for performing initial tests for drugs and drug metabolites at licensee testing facilities. The proposed paragraph would group together in one paragraph the current requirements that are dispersed throughout the rule to meet Goal 6 of this rulemaking, which is to improve clarity in the organization of the rule.

Proposed §26.137(e)(1) would amend the first sentence of current Section 2.7(e)(1) in Appendix A to Part 26 but retain the intent of the current provision as it applies to licensee testing facilities. The current and proposed paragraphs require licensee testing facilities to use only immunoassay tests that meet the requirements of the Food and Drug Administration for commercial distribution. The requirements in the current paragraph related to initial drug

testing at HHS-certified laboratories would be moved to §26.167(d)(1) of proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] to improve organizational clarity in the rule.

In addition, the proposed paragraph would prohibit licensee testing facilities from relying on drug test results from any devices they may use to perform validity screening tests. This proposed prohibition would be added because several non-instrumented devices are available that combine tests for the presence of drugs and drug metabolites in a urine specimen with tests for other attributes of a urine specimen, such as creatinine concentration. The proposed rule would permit licensee testing facilities to use such combination devices for validity screening tests, if the devices meet the requirements of proposed §26.137(b)(1). However, the drug testing capabilities of these devices are not yet sufficiently accurate and sensitive to be used in Part 26 programs, in which licensees and other entities would be permitted to administratively withdraw an individual's authorization on the basis of positive initial drug test results for marijuana and cocaine metabolites. The NRC may consider accepting the use of initial drug test results from non-instrumented devices in a future rulemaking, when HHS publishes a final revision to the Mandatory Guidelines that establishes requirements for their use in Federal workplace drug testing programs. At this time, however, the proposed rule would retain the current prohibition on using such devices for drug testing at licensee testing facilities.

Proposed §26.137(e)(2) would be added to require licensee testing facilities to either discard specimens that yield negative results from initial tests at the licensee testing facility or pool them and use these specimens as quality control specimens, if the specimens are certified as drug negative and valid by an HHS-certified laboratory. The proposed paragraph would incorporate the related provision from the HHS Guidelines and would be added to meet Goal 1

of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.137(e)(3) would permit licensee testing facilities to conduct multiple tests of a single specimen for the same drug or drug class. The requirements in the proposed paragraph would also be consistent with a similar provision in the HHS Guidelines and would be added for the same reasons discussed with respect to §26.137(e)(2).

Proposed §26.137(e)(4) would amend the first sentence of current Section 2.8(b) in Appendix A to Part 26, which states that licensee testing facilities are not required to assess their false positive rates in drug testing. The proposed paragraph would retain the intent of the current requirement, but the terminology used in the paragraph would be revised to use the new terms that are used throughout the proposed rule, e.g., “initial” rather than “screening,” as discussed with respect to proposed §26.5 [Definitions].

Proposed §26.137(e)(5) would amend the second sentence of current Section 2.8(b) in Appendix A to Part 26, which requires licensee testing facilities to submit specimens that yield negative results from initial testing to the HHS-certified laboratory as a quality control check on the licensee testing facility’s drug testing process. The proposed paragraph would retain the intent of the current provision but make several changes to the specific requirements.

The proposed paragraph would use the term, “analytical run,” rather than the current term, “test run,” to reflect changes in testing technologies that some licensee testing facilities have adopted since the current rule was published. Requirements for blind performance and other quality control testing in the current rule were based on the assumption that specimens would be tested in batches. However, many licensee testing facilities now conduct continuous testing, and no longer test specimens in batches. Therefore, the proposed rule would use the term, “analytical run,” to refer to both batch and continuous processing, as defined in proposed

§26.5 [Definitions]. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

The current rule does not establish a number or percentage of negative specimens that licensee testing facilities are required to submit to the HHS-certified laboratory for performance testing, which has raised implementation questions from licensees who have wanted to know how many specimens must be submitted. Therefore, to clarify the current requirement to "submit a sampling of specimens," the proposed rule would require licensee testing facilities to forward at least one specimen that yields negative drug test results from each analytical run to the HHS-certified laboratory for performance testing. The proposed paragraph would also establish 5 percent of the specimens tested in each analytical run as the percentage of negative specimens that the licensee testing facility must submit to the HHS-certified laboratory for testing, except if 5 percent of an analytical run would be a number less than one specimen. In the latter case, the licensee testing facility would submit at least one negative specimen from the analytical run. The proposed requirement would ensure the ongoing evaluation of the accuracy of the licensee testing facility's initial drug testing without imposing a large performance testing burden.

The proposed rule would move the requirement for testing blind performance test samples in current Section 2.8(b) in Appendix A to Part 26 to proposed §26.137(d)(7). The last sentence of the current paragraph, which addresses performance testing of breath analysis equipment for alcohol testing, would be moved to proposed §26.91(e) in Subpart E [Collecting Specimens for Testing]. The proposed rule would reorganize the current requirements and group them with related requirements to meet Goal 6 of this rulemaking, which is to improve clarity in the organization of the rule.

Proposed §26.137(e)(6) would amend the requirements of current Section 2.8(c) in Appendix A to Part 26 and apply them to licensee testing facilities. The proposed rule would apply requirements for quality controls to licensee testing facilities to provide greater assurance that initial drug tests performed by these facilities provide accurate results. The increased performance testing would be necessary because the proposed rule permits licensees and other entities to rely on test results from other Part 26 programs to a greater extent that the current rule. Therefore, it is necessary to ensure that any tests performed at licensee testing facilities meet minimum standards. This proposed change would meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs.

Proposed §26.137(e)(6)(i)–(e)(6)(iii) would be added to describe the required characteristics of the quality control samples that the licensee testing facility must include in each analytical run of specimens. The proposed paragraphs would require each analytical run to include at least one negative quality control sample as well as quality control samples targeted at 25 percent above the cutoff and at 75 percent of the cutoff level for each drug and drug metabolite for which testing is conducted. The proposed requirements would be consistent with the requirements for processing quality control samples during initial drug testing in the HHS Guidelines.

Proposed §26.137(e)(7) would establish requirements for the number of quality control samples to be included in each analytical run at the licensee testing facility. The proposed rule would require that a minimum of 10 percent of the specimens in each analytical run must be quality control samples. The quality control samples included in the run could be any combination of the types of quality control samples specified in proposed §26.137(d)(6))(i)–(d)(6)(iii). However, the proposed paragraph would require that one percent or at least one of the quality control samples included in each run must be a blind performance

test sample. For example, if an analytical run tested 50 donor specimens, the licensee testing facility would include 5 quality control samples in the run. At least one of the 5 would be required to be a blind test sample, and it could be either a blank or a sample fortified with a drug or metabolite at either 25 percent above the FFD program's cutoff level or at 75 percent of the cutoff level. The remaining 4 samples could include any combination of blanks and fortified samples. Licensee testing facilities would be expected to vary the drugs and drug metabolites used to fortify the quality control samples. The licensee testing facility would not send the quality control samples to the HHS-certified laboratory for testing, but use them for internal quality control purposes only. The proposed requirements in this paragraph would incorporate the related requirements in the HHS Guidelines and would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.137(e)(8) would extend to licensee testing facilities the existing requirement in the third sentence of the last paragraph of current Section 2.8(c) in Appendix A to Part 26, which requires HHS-certified laboratories to implement procedures to ensure that carryover does not contaminate the testing of a donor's specimen and to document the procedures. The proposed rule would extend this requirement to licensee testing facilities because it is a standard forensic practice that is necessary to ensure the integrity of the testing process.

Proposed §26.137(f) [Errors in testing] would be added to require licensees and other entities who maintain testing facilities to investigate any errors or unsatisfactory performance of the testing process, identify the cause(s) of the adverse conditions, and correct them. The proposed rule would require the licensee or other entity to document the investigation and any corrective actions taken. The proposed revision would clarify that licensees must investigate

any testing errors or unsatisfactory performance identified throughout the testing process or during the review process that would be required under proposed §26.91 [Review process for fitness-for-duty policy violations]. The NRC intended, in the original rule, that testing or process errors discovered in any part of the program, including through the review 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 proposed paragraph would also require the cause of the condition be determined and corrective action be taken and documented for consistency with Criterion XVI in Appendix B of 10 CFR Part 50.

Proposed §26.137(g) [Accuracy] would retain current Section 2.7(o)(3)(i) in Appendix A to Part 26, which requires checking the instruments used in testing for accuracy, as it applies to licensee testing facilities. The proposed rule would move the current requirement as it relates to HHS-certified laboratories to §26.167(h) in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity.

Proposed §26.137(h) [Calibrators and controls] would update current Section 2.7(o)(2) in Appendix A to Part 26, which establishes requirements for the standards and quality control samples used for performance testing. At the time the original paragraph was written, most laboratories prepared their own standards and controls. In the ensuing years, the number and variety of sources for materials used in performance testing have increased. The proposed paragraph would update the existing requirements to refer to several of the alternatives, including, but not limited to, pure drug reference materials, stock standard solutions from other laboratories, and standard solutions obtained from commercial manufacturers. The proposed requirements in this paragraph would incorporate the related requirements in the HHS

Guidelines and would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.139 Reporting initial validity and drug test results

A new §26.139 [Reporting initial validity and drug test results] would combine existing requirements related to the reporting and management of test results from the licensee testing facility that are interspersed throughout current Appendix A to Part 26. This proposed change would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization of the rule, by grouping related requirements together in a single section.

Proposed §26.139(a) would amend current Section 2.7(g)(2) in Appendix A to Part 26, which establishes requirements for the manner in which HHS-certified laboratories and licensee testing facilities must report test results to licensee management. The requirements in the current paragraph that are related to reporting test results from HHS-certified laboratories would be moved to §26.169(b) of proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity. The proposed paragraph would delete the current reference to “special processing” and replace it with reference to validity test results, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.139(b) would amend the last sentence of current §26.24(d)(1), which specifies the individuals to whom results of initial tests from the licensee testing facility may be released. The proposed paragraph would add the MRO’s staff to the list of individuals who would be permitted to have access to the results of initial tests performed at the licensee testing facility consistent with the addition of this job role to the proposed rule. Individuals who are

serving as MRO staff members would require access to initial test results from a licensee's testing facility in the course of performing their administrative duties for the MRO.

Proposed §26.139(c) would amend current Section 2.7(o)(5) in Appendix A to Part 26. The requirements in the current paragraph that address the availability of personnel to testify in proceedings related to drug test results from an HHS-certified laboratory would be moved to §26.153(f)(2) of proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity. The proposed rule would move the current requirement for licensee testing facility personnel to be available to testify at any proceedings with respect to breath analysis test results to proposed §26.85(d) because licensee testing facilities are typically not responsible for quality control of alcohol testing, which is conducted at the collection site.

Proposed §26.139(d) would amend the portions of current Section 2.7(g)(6) in Appendix A to Part 26 that apply to the summary report that licensee testing facilities must provide to FFD program management. The current requirement for the licensee testing facility to prepare a monthly report of test results would be replaced with a proposed requirement for the licensee testing facility to summarize the data annually in the FFD program performance report required in proposed §26.217(b). Experience implementing the current requirement for a monthly statistical summary has indicated that the monthly summary has not been as useful to licensees for ongoing monitoring of testing program effectiveness as other mechanisms that licensees have developed. Therefore, the requirement in proposed §26.139(f) for FFD program management to monitor the ongoing effectiveness of the licensee testing facility testing program would replace the monthly reporting requirement in Section 2.7(g)(6). This proposed change would meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements. The requirements in the current paragraph that address

summary reports from HHS-certified laboratories would be moved to §26.169(k) of proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity.

Proposed §26.139(e) would amend current Section 2.7(g)(7) in Appendix A to Part 26, which requires licensee testing facilities and HHS-certified laboratories to report test results for both the cutoff levels specified in this part and any more stringent cutoff levels used by the FFD program. The current requirement related to HHS-certified laboratories would be relocated to §26.169(c) of proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity. The proposed rule would require licensees and other entities who operate testing facilities, and have adopted more stringent cutoff levels for initial tests for drugs and drug metabolites than those specified in proposed §26.133 [Cutoff levels for drugs and drug metabolites], to conduct tests and report test results based only on their more stringent cutoff levels. The basis for the current requirement to conduct tests and report test results for the cutoff levels specified in this part, when the licensee is using more stringent cutoff levels, was a method by which the NRC monitored licensee implementation of the permission to use more stringent cutoff levels. The proposed rule would eliminate this requirement, because proposed §26.31(d)(3)(iii)(C) would require a qualified forensic toxicologist to certify the scientific and technical validity of the licensee's or other entity's testing process at any lower cutoff levels. Therefore, the testing and reporting requirement would no longer be needed to monitor licensee testing facility performance in this area. The proposed rule would continue to require licensee testing facilities to report test results (and the cutoff levels used) from testing for additional drugs and drug metabolites, beyond those specified in proposed §26.31(b)(1).

Proposed §26.139(f) would be added to require FFD program management to monitor the ongoing effectiveness of the licensee testing facility testing program. The proposed rule would provide examples of the types of information and possible program performance indicators that licensees and other entities may use for program monitoring. The proposed rule would also require FFD program management to make adjustments to the testing program in response to information gained from the ongoing monitoring. The proposed requirements would replace the current monthly summary reporting requirement in current Section 2.7(g)(7) in Appendix A to Part 26 to strengthen FFD programs by ensuring that licensees monitor licensee testing facility performance on an ongoing basis and correct any weaknesses as they are identified. The proposed paragraph also would be consistent with the NRC's performance-based approach to regulation. This proposed change would meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs, as discussed in Section IV. B.

Subpart G – Laboratories Certified by the Department of Health and Human Services

Section 26.151 Purpose

Proposed §26.151 [Purpose] would be added to introduce the purpose of the proposed subpart, which is to establish requirements for the HHS-certified laboratories that licensees and other entities must use for testing urine specimens for validity and the presence of drugs and drug metabolites. This proposed section would be added to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule. The majority of the requirements in this proposed subpart would be based upon the current requirements in Appendix A to Part 26, as they relate to HHS-certified laboratories. However, the current requirements would be updated to be consistent with the Department of Health and Human

Services' revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines), as published in the Federal Register on April 13, 2004 (69 FR 19643).

Section 26.153 Using certified laboratories for testing urine specimens

A new §26.153 [Using certified laboratories for testing urine specimens] would be added to present together requirements related to the use of HHS-certified laboratories by licensees and other entities who would be subject to the rule

Proposed §26.153(a) would combine and update current requirements for licensees and other entities to use HHS-certified laboratories for initial and confirmatory drug testing of urine specimens. The proposed paragraph would relocate and combine current §26.24(f), the second sentence of Section 1.1(3), and Section 4.1(a) in Appendix A to Part 26, which require licensees and other entities to use HHS-certified laboratories for drug testing. The proposed change would be made to eliminate redundancies in the current rule and improve organizational clarity. The proposed paragraph would update the current citations for the HHS Guidelines because the Guidelines have been amended several times since the current rule was published. In addition, the proposed rule would provide current contact information for obtaining information about the certification status of HHS-certified laboratories because the contact information also has changed since the current rule was published. The proposed paragraph would also add a requirement for licensees and other entities to use HHS-certified laboratories for initial and confirmatory validity testing, consistent with the addition of urine specimen validity testing requirements to the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The cross-reference to current §26.24(d), which permits licensee testing facilities to conduct initial drug tests, would be updated to reference the related provision in the proposed rule, proposed §26.31(d)(3)(ii).

Proposed §26.153(b) would amend the first sentence of current Section 2.7(l)(2) in Appendix A to Part 26, which requires HHS-certified laboratories to have the capability, at the same laboratory premises, of performing initial and confirmatory tests for any drug and drug metabolite for which service is offered and confirmatory testing of blood for alcohol concentrations. The current requirement for HHS-certified laboratories to be capable of conducting confirmatory alcohol testing of blood would be deleted for the reasons discussed with respect to proposed §26.83(a). The proposed paragraph would add a requirement for HHS-certified laboratories to have the capability to perform both initial validity and confirmatory validity tests at the same premises for consistency with the addition of requirements to perform validity testing to the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The second sentence of current Section 2.7(l)(2), which establishes requirements for the capabilities of licensee testing facilities, would be moved to proposed §26.123 [Licensee testing facility capabilities] of Subpart F [Licensee Testing Facilities] for organizational clarity. The last sentence of the current paragraph, which permits the testing of breath specimens for alcohol at the collection site, would be deleted because the proposed rule would address alcohol testing in Subpart E [Collecting Specimens for Testing]. These organizational changes to the current paragraph would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.153(c) would amend the first sentence of current Section 2.7(k) in Appendix A to Part 26, which restricts HHS-certified laboratories from subcontracting unless authorized by the licensee. The proposed rule would extend this restriction to subcontracting for specimen validity testing for consistency with the addition of requirements to perform validity testing to the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The second sentence of current Section 2.7(k) would be deleted from the proposed paragraph for

several reasons: First, the requirement to have the capability to test for marijuana, cocaine, opiates, phencyclidine, and amphetamines would be deleted because it is redundant with proposed §26.31(d)(1). The requirement to be capable of testing whole blood would be deleted because the proposed rule would no longer permit donors to request confirmatory alcohol testing of blood for the reasons discussed with respect to proposed §26.83(a). Finally, the requirement for laboratories to be capable of conducting GC/MS testing would be eliminated because HHS-certified laboratories would be permitted to use other methods of confirmatory testing, consistent with related revisions to the HHS Guidelines.

Proposed §26.153(d) would amend current Section 4.1(b) in Appendix A to Part 26, which requires licensees and C/Vs to use only HHS-certified laboratories who agree to follow the same rigorous testing, quality control, and chain-of-custody procedures when testing for more stringent cutoff levels, additional drugs to those for which testing required under Part 26, and blood. The proposed paragraph would eliminate reference to testing for blood because the proposed rule would no longer permit donors to request confirmatory alcohol testing of blood for the reasons discussed with respect to proposed §26.83(a).

Proposed §26.153(e) would amend the third sentence of current Section 2.7(m) in Appendix A to Part 26, which requires licensees to conduct an inspection and evaluation of a laboratory's drug testing operations before using the laboratory's services. Some licensees have incorrectly interpreted the current regulation as requiring licensee employees to perform the pre-award inspection and evaluation. In many cases, however, appropriately qualified licensee employees may not be available to perform the inspection and evaluation, and the use of contracted experts may be necessary to achieve the NRC's intent. The proposed paragraph would revise the current requirement to indicate that licensees and other entities would be responsible "to ensure" that the inspection and evaluation is performed, in order to clearly

indicate that the use of expert contractors is acceptable. In addition, the proposed rule would clarify that the pre-award inspection and evaluation must be performed by qualified individuals.

Proposed §26.153(e) also would permit a licensee or other entity to begin using the services of another HHS-certified laboratory immediately, without a pre-award evaluation and inspection, in the event that the licensee's or other entity's primary laboratory loses its certification. To be considered acceptable, the proposed rule would require that the replacement laboratory must be in use by another Part 26 program. The proposed rule would add this provision to ensure that testing can continue, in the event that the HHS-certified laboratory upon which a licensee or other entity relies loses its certification, as some licensees have experienced. Related requirements for auditing the replacement laboratory would be specified in proposed §26.41(g)(5).

Proposed §26.153(f) would be added to require that licensees' and other entities' contracts with HHS-certified laboratories must require the laboratories to implement the applicable requirements of this part. Because the NRC does not regulate HHS-certified laboratories, this revision would ensure that the Agency has a legal basis for requiring HHS-certified laboratories to comply with this part when conducting testing for licensees and other entities.

Proposed §26.153(f)(1) would retain the requirement in current Section 2.7(l)(1) in Appendix A to Part 26, which states that HHS-certified laboratories must comply with applicable State licensor requirements. The proposed paragraph would replace the term, "HHS-certified laboratories," with the term, "laboratory facilities," to clarify that State requirements apply to laboratory facilities rather than to the HHS-certified laboratory as a corporate entity. The proposed clarification would be necessary because some HHS-certified laboratories are operated by large national corporations with facilities in several different States, and only the

facilities in a specific State would be required to meet the requirements of that State. The proposed change would be made for clarity in the language of the proposed rule as well as consistency with the HHS Guidelines.

Proposed §26.153(f)(2) would amend current Section 2.7(o)(5) in Appendix A to Part 26, which requires that HHS-certified laboratories must make available qualified personnel to testify in proceedings based on urinalysis results reported by the laboratory. Reference to licensee testing facilities would be moved to §26.139(c) in proposed Subpart F [Licensee Testing Facilities] for organizational clarity. The requirement for qualified personnel to be available to testify in proceedings related to breath analysis results would be moved to proposed §26.85(d) in proposed Subpart E [Collecting Specimens for Testing] for organizational clarity and because responsibility for testifying with respect to breath analysis results would reside with the licensee's or other entity's collection site personnel.

Proposed §26.153(f)(3) would update current Section 3.1 in Appendix A to Part 26, which requires HHS-certified laboratories to protect donors' records. The current requirement for licensee testing facilities to protect donors' records would be subsumed within the second sentence of proposed §26.37(a) for organizational clarity. The cross-reference to current §26.29 would be updated to reference proposed §26.39 [Protection of information].

Proposed §26.153(f)(4) would update current Section 3.2 in Appendix A to Part 26. Specifically, the proposed rule would add a reference to Sec. 503 of Pub. L. 100-71 to document the basis for this requirement, which would be adapted from the HHS Guidelines. The proposed paragraph would add a requirement for a donor to have access to records relating to his or her validity test results for consistency with the addition of validity testing requirements to the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The proposed paragraph would delete the current reference to records related to alcohol test results

because HHS-certified laboratories would no longer be testing blood specimens for alcohol, as discussed with respect to proposed §26.83(a).

Proposed §26.153(f)(5) would be added to clarify that HHS-certified laboratories must avoid relationships with a licensee's or other entity's MRO(s) that may be construed as a potential conflict of interest. The proposed paragraph would respond to the experiences of other Federal agencies regarding apparent conflicts of interest involving laboratories and MROs. Although the NRC is not aware of any situations of this type in Part 26 programs, the integrity of the MRO function is sufficiently important that incorporating this requirement would be warranted to prevent potential conflict of interest concerns. The proposed paragraph would be consistent with the related provision in the HHS Guidelines.

Proposed §26.153(f)(6) would amend the requirements in the first two sentences of current Section 2.7(m) in Appendix A to Part 26, which require HHS-certified laboratories to permit the NRC, licensees, and other entities to conduct inspections at any time, including unannounced inspections. The proposed rule would delete, for organizational clarity, the existing references to collection site services and licensee testing facilities, which would be covered under proposed §26.221[Inspections]. The proposed paragraph would also delete reference to confirmatory testing of blood specimens for alcohol because HHS-certified laboratories would no longer be testing blood specimens for alcohol, as discussed with respect to proposed §26.83(a).

Proposed §26.153(g) would require licensees and other entities to provide a memorandum for the record to the HHS-certified laboratories that they use to document why the licensee or other entity is using a non-Federal custody-and-control form. Under the HHS Guidelines, laboratories may reject any specimen that is submitted for testing with a non-Federal custody-and-control form unless the licensee or other entity provides a memorandum

for the record. The proposed paragraph would be necessary to prevent licensee's and other entity's specimens from being rejected.

Section 26.155 Laboratory personnel

Proposed §26.155 [Laboratory personnel] would update current Section 2.5 in Appendix A to Part 26 to be consistent with revisions to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) published in the Federal Register on April 13, 2004 (69 FR 19643).

Proposed §26.155(a) [Day-to-day management of the HHS-certified laboratory] would amend current Section 2.5(a)(1) in Appendix A to Part 26, which requires the HHS-certified laboratory to have a qualified individual to assume responsibility for day-to-day management of the HHS-certified laboratory. Specifically, the proposed paragraph would replace the term, "qualified individual," with the term, "responsible person," for consistency with terminology that other Federal agencies use to refer to this job role.

Proposed §26.155(a) would retain the majority of Section 2.5(a)(2), which establishes qualification requirements for the responsible person. Proposed §26.155(a)(1)(i)–(a)(1)(iv) would retain current Section 2.5(a)(2)(i)–(a)(2)(iv) in Appendix A to Part 26, with minor grammatical changes that would be consistent with similar changes to the related provisions in the HHS Guidelines.

Proposed §26.155(a)(2) and (a)(3), which establish minimum day-to-day management responsibilities of the responsible person, would retain current Section 2.5(a)(4) and (a)(5) in Appendix A to Part 26.

Proposed §26.155(a)(4) would amend current Section 2.5(a)(5) in Appendix A to Part 26, which relates to the responsible person's responsibility to maintain the laboratory's procedures manual. The proposed paragraph would eliminate the current requirement for the procedures to be maintained in a laboratory manual as unnecessarily restrictive. Laboratories would be permitted to use other means to maintain their procedures. The proposed paragraph would retain the current requirements in the second and third sentences of Section 2.5(a)(5) in Appendix A to Part 26, which require the responsible person to review, sign, and date the procedures when they are first placed in use, changed, or a new individual assumes responsibility for management of the laboratory, and maintain copies of them. The current cross-reference to Section 2.7(o) in Appendix A to Part 26 would be updated to reference proposed §26.157 [Procedures], consistent with the organizational changes made to the rule.

Proposed §26.155(a)(5) and (a)(6) would retain current Section 2.5(a)(6) and (a)(7) in Appendix A to Part 26, which define the responsible person's responsibilities with respect to maintaining a quality assurance program and taking remedial actions to maintain satisfactory laboratory operations.

Proposed §26.155(b) [Certifying scientist] would amend current Section 2.5(b) in Appendix A to Part 26 to be consistent with changes made to the related requirement in the HHS Guidelines. Consistent with the HHS Guidelines, the proposed rule would provide more detailed requirements with respect to the individual who validates test results at the HHS-certified laboratory before they are transmitted to the licensee's or other entity's MRO. In proposed §26.155(b)(1), a new job title, "certifying scientist," would replace the term, "qualified individual(s)," in the first sentence of current Section 2.5(b) in Appendix A to Part 26 for consistency with a related change in the HHS Guidelines. Proposed §26.155(b)(2) would specify the required qualifications of individuals who serve as certifying scientists. Proposed

§26.155(b)(3) would permit laboratories to use more than one certifying scientist with differing responsibilities.

Proposed §26.155(c) [Day-to-day operations and supervision of analysts] would retain current Section 2.5(c) in Appendix A to Part 26. The proposed rule would make minor wording changes to the current paragraph to increase the consistency of the wording in this provision with that of the related provision in the HHS Guidelines.

Proposed §26.155(d) [Other personnel] and (e) [Training] would retain current Section 2.5(d) and (e) in Appendix A to Part 26, respectively.

Proposed §26.155(f) [Files] would amend current Section 2.5(f) in Appendix A to Part 26. The proposed revisions would be consistent with related requirements in the HHS Guidelines. The current requirement for records of tests for color blindness would be eliminated, consistent with a similar change to the HHS Guidelines. Tests for color blindness would no longer be necessary because current testing technologies provide means, other than color, for reading test results.

Section 26.157 Procedures

A new §26.157 [Procedures] would reorganize and amend requirements for procedures, which are interspersed throughout current Appendix A to Part 26, including requirements contained in current Sections 2.2 and 2.7 in Appendix A to Part 26. The proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve organizational clarity by grouping procedural requirements for HHS-certified laboratories in one section.

Proposed §26.157(a) would make minor editorial changes to the first sentence of current Section 2.2 in Appendix A to Part 26, which requires licensee testing facilities and HHS-

certified laboratories to have detailed procedures for conducting testing. The proposed rule would delete the current reference to blood samples because donors would no longer have the option to request blood testing for alcohol, as discussed with respect to proposed §26.83(a). Reference to licensee testing facilities would be moved to proposed §26.127(a) in Subpart F [Licensee Testing Facilities] for organizational clarity. The proposed rule would also delete reference to procedures for specimen collections, because procedural requirements for specimen collections would be relocated to proposed Subpart E [Collecting Specimens for Testing].

Proposed §26.157(b) would combine and amend portions of the requirements in the first sentence of current Sections 2.4(d) and 2.7(a)(2) in Appendix A to Part 26 related to the content and implementation of specimen chain-of-custody procedures. The proposed paragraph would retain the portions of the current paragraphs that require HHS-certified laboratories to develop, implement, and maintain written chain-of-custody procedures to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to another HHS-certified laboratory, and continuing until final disposition of the specimens. The current requirements related to licensee testing facilities would be moved to proposed §26.127(b) in Subpart F [Licensee Testing Facilities] for organizational clarity. The proposed rule would also remove references to custody-and-control procedures for blood specimens because donors would no longer have the option to request blood testing for alcohol, as discussed with respect to proposed §26.83(a).

Proposed §26.157(c) would amend the portions of current Section 2.7(o)(1) in Appendix A to Part 26 that address the required content of procedures for HHS-certified laboratories. The proposed paragraph would retain the portions of the current provision that require laboratories to develop and maintain procedures to specify all of the elements of the

testing process, including, but not limited to, the principles of each test and the preparation of reagents, standards, and controls. The proposed paragraph would present the required topics of the procedures in a list format in proposed §26.157(c)(1)–(c)(12) to clarify that each topic stands on its own. The proposed paragraph would eliminate the current requirement for the procedures to be maintained in a laboratory manual, which is unnecessarily restrictive. HHS-certified laboratories would be permitted to use other means to maintain their procedures. For organizational clarity, two portions of the current provision would be moved to other subparts of the proposed rule that address related topics. Requirements for licensee testing facility procedures would be moved to §26.127(c) in proposed Subpart F [Licensee Testing Facilities]. In addition, the proposed rule would move the last two sentences of current Section 2.7(o)(1), which specify records retention requirements, to §26.215(b)(4) of proposed Subpart J [Recordkeeping and Reporting Requirements].

Proposed §26.157(d) would amend current Section 2.7(o)(3)(iii) in Appendix A to Part 26, which requires procedures for the setup and normal operation of testing instruments; a schedule for checking critical operating characteristics for all instruments; tolerance limits for acceptable function checks; and instructions for major troubleshooting and repair. The proposed rule would make three changes to the current provision for organizational clarity. The proposed paragraph would present the required topics of the procedures in a list format in proposed §26.157(d)(1)–(d)(3) to clarify that each topic stands on its own. The current requirement to maintain records of preventative maintenance would be relocated to proposed §26.215(b)(10) in Subpart J [Recordkeeping and Reporting Requirements]. And, the current requirements that apply to licensee testing facilities would be moved to §26.127(d) in proposed Subpart F [Licensee Testing Facilities].

Proposed §26.157(e) would amend current Section 2.7(o)(4) in Appendix A to Part 26, which requires documented corrective actions if systems are out of acceptable limits or errors are detected. The requirements in the current paragraph that apply to licensee testing facilities would be moved to §26.127(e) in proposed Subpart F [Licensee Testing Facilities] for organizational clarity.

Section 26.159 Assuring specimen security, chain of custody, and preservation

Proposed §26.159 [Assuring specimen security, chain of custody, and preservation] would be added to present in one section the requirements of the proposed rule that apply to HHS-certified laboratories with respect to the safeguarding of specimen identity, integrity, and security. The proposed organizational change would be made because requirements that address these topics are dispersed throughout the current rule and grouping them together in a single section would make them easier to locate.

Proposed §26.159(a) would amend current Section 2.7(a)(1) in Appendix A to Part 26. Proposed §26.159(a) would retain the first three sentences of current Section 2.7(a)(1) in Appendix A to Part 26, which require HHS-certified laboratories to be secure and accessible only to authorized personnel. For organizational clarity, the requirements that apply to licensee testing facilities would be moved to proposed §26.129(a) in Subpart F [Licensee Testing Facilities], and the last sentence of the current paragraph, which establishes recordkeeping requirements, would be moved to §26.215(b)(13) in proposed Subpart J [Recordkeeping and Reporting Requirements]. In addition, the last sentence of the proposed paragraph would be revised for increased clarity in the requirement and would expand the list of persons who would be authorized to have access to the laboratory to include representatives of the Secretary of the

Department of Health and Human Services and emergency responders. This proposed change would be made for consistency with the related provision in the HHS Guidelines.

Proposed §26.159(b) would amend current Section 2.7(b)(1) in Appendix A to Part 26, which establishes requirements for receiving specimens at the HHS-certified laboratory and assuring their integrity and identity. The proposed rule would retain the existing requirement for the HHS-certified laboratory to report evidence of tampering to licensees' or other entities' management within 24 hours of discovery, as well as the requirement for the laboratory to document any evidence of tampering on the specimen's custody-and-control form. The proposed rule would move the current requirements related to licensee testing facilities to §26.129(b) in proposed Subpart F [Licensee Testing Facilities] for organizational clarity. Several requirements would also be added to the proposed paragraph.

The proposed paragraph would require licensee or other entity management personnel to ensure that an investigation is initiated if any indications of specimen tampering are identified, and take corrective actions if tampering is confirmed. The appropriate corrective actions would depend upon the nature of the tampering identified as a result of the investigation. For example, if the investigation indicated that the tampering was an attempt to subvert the testing process and the persons involved were identified, licensee and other entity management personnel would impose the sanctions in proposed §26.75(b) for a subversion attempt. The proposed paragraph would also require the licensee, other entity, or HHS-certified laboratory to correct any systematic weaknesses in specimen custody-and-control procedures that may be identified in the investigation, such as inadequate safeguarding of specimen shipping containers. The proposed rule would add this provision because some licensees have not investigated or taken corrective actions in response to indications of tampering with specimens under the current rule.

The proposed paragraph would also prohibit testing specimens if there is a reason to believe that the specimens have been altered in such a manner as to affect specimen identity and integrity. In these circumstances, the proposed rule would require the licensee or other entity to collect another specimen from the donors. Although the NRC is not aware of any instances in which such circumstances have arisen in Part 26 programs, the experience of other Federal agencies indicates such tampering is possible. Therefore, the proposed requirement would ensure that individuals would not be subject to sanctions for a non-negative test result from a specimen that may not have been theirs. The proposed change would meet Goal 7 of this rulemaking, which is to protect the due process rights of individuals who are subject to Part 26. The additional provision would also be consistent with the requirements of other Federal agencies.

Proposed §26.159(c) would update and combine current Section 2.7(b)(2) with portions of current Sections 2.9(n) and 3.1 in Appendix A to Part 26, which establish requirements for chain-of-custody procedures for specimens and aliquots at licensee testing facilities and HHS-certified laboratories. The proposed rule would move the requirements in the current paragraphs that are related to licensee testing facilities to §26.129(c) in proposed Subpart F [Licensee Testing Facilities] for organizational clarity. Proposed §26.159(c) would also include the requirements in current Sections 2.9(n) and 3.1 in Appendix A to Part 26, which require the laboratory to maintain the original specimen and custody-and-control form in secure storage at the HHS-certified laboratory. The proposed changes would be made to reduce redundancies and improve the organization clarity of the rule.

Proposed §26.159(d) and (e) would update the portions of current Section 2.7(a)(2) in Appendix A to Part 26 that establish requirements for HHS-certified laboratory personnel to maintain and document the chain of custody for specimens and aliquots, by replacing the

current paragraph with two related provisions from the HHS Guidelines. Proposed paragraph (d) in this section would require the laboratory's internal custody-and-control form to allow for identification of the donor, and documentation of the testing process and transfers of custody of the specimen. The phrase, "within the laboratory," would be added to proposed paragraph (e) to clarify that the requirement to document each instance of the handling and transfer of specimens applies to internal laboratory activities and does not apply to transfers involving couriers. The proposed rule would relocate the requirements in the current paragraph that are related to licensee testing facilities to §26.129(d) and (e) in proposed Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity.

Proposed §26.159(f) and (g) would separate current Section 2.4(i) in Appendix A to Part 26 into two paragraphs, for the reasons discussed with respect to the similar provisions of proposed §26.117(i) and (k) and §26.129(g) and (h). The proposed paragraphs would repeat the requirements for packaging and shipping non-negative specimens that would be presented in proposed §26.117(i) and (k) of Subpart E [Collecting specimens for testing] and §26.129(g) and (h) in Subpart F [Licensee Testing Facilities], but apply them to packaging and shipping specimens from one HHS-certified laboratory to another. The bases for these requirements are discussed with respect to proposed §26.117(i) and (k).

Proposed §26.159(h) [Short-term refrigerated storage] would replace current Section 2.7(c) in Appendix A to Part 26, which establishes requirements for refrigerating urine specimens at the HHS-certified laboratory and licensee testing facility to protect them from degradation. The proposed rule would replace the current paragraph with the simplified language of the related provision in the HHS Guidelines. Requirements related to short-term refrigerated storage at licensee testing facilities would be moved to §26.129(f) in proposed Subpart F [Licensee Testing Facilities] for organizational clarity.

Proposed §26.159(i) [Long-term storage] would amend current Section 2.7(h) in Appendix A to Part 26, which establishes requirements for long-term frozen storage of positive urine specimens at HHS-certified laboratories and licensee testing facilities. Requirements related to long-term storage of specimens by licensee testing facilities would be moved to proposed §26.135(c) in Subpart F [Licensee Testing Facilities] for organizational clarity. The proposed paragraph would add requirements for storing specimens that yield non-negative validity test results, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The reference to "administrative or disciplinary proceedings" in the first sentence of the current paragraph would be eliminated because there are other circumstances in which it may be necessary to have a specimen available for restesting, including, but not limited to, retesting an aliquot of an invalid specimen at a second HHS-certified laboratory under proposed §26.161(g) [Additional testing by a second laboratory]. The proposed rule would also update the terminology used in the current paragraph by adding a reference to "Bottle B" of a split specimen and replacing the term, "positive," with the term, "non-negative," to be consistent with the new terminology adopted throughout the proposed rule. As discussed with respect to proposed §26.5 [Definitions], these proposed changes in terminology would be made to improve clarity in the language of the proposed rule.

Proposed §26.159(j) would be added to incorporate related changes to the HHS Guidelines. The proposed paragraph would permit the HHS-certified laboratory to discard negative specimens. The proposed paragraph also would permit laboratories to pool specimens that are certified to be negative for drugs and drug metabolites and valid, as well as use them as quality control samples, as permitted under the HHS Guidelines.

Section 26.161 Cutoff levels for validity testing

A new §26.161 [Cutoff levels for validity testing] would be added to establish maximum cutoff levels and methods for conducting specimen validity testing at HHS-certified laboratories, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The proposed rule would incorporate these requirements from the HHS Guidelines as revised on April 13, 2004 (69 FR 19644) to meet, in part, Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.161(a) [Validity test results] would be added to specify that laboratories must conduct initial and confirmatory validity testing using two different aliquots of a urine specimen.

Proposed §26.161(b) [Initial validity testing] would be added to establish requirements and cutoff levels for initial validity tests to be performed at HHS-certified laboratories.

Proposed §26.161(b)(1)–(b)(6) would establish requirements for validity tests that HHS-certified laboratories must conduct on a primary specimen, which would be either a single specimen submitted by an FFD program that does not follow split specimen procedures, or the specimen contained in Bottle A of a split specimen. For initial validity tests of each specimen, HHS-certified laboratories would determine the creatinine concentration of each specimen in proposed §26.161(b)(1)(i). If the creatinine concentration is less than 20 mg/dL, the laboratory would determine the specimen's specific gravity in proposed §26.161(b)(1)(ii). Proposed §26.161(b)(1)(iii) would require the laboratory to determine each specimen's pH. Proposed §26.161(b)(1)(iv) would require the laboratory to test the specimen for the presence of oxidizing adulterants, and proposed §26.161(b)(1)(v) would require additional validity testing, depending upon the characteristics of the specimen.

Proposed §26.161(b)(2)(i)–(b)(2)(ix) would establish the criteria for determining whether a specimen must be subject to confirmatory validity testing.

Proposed §26.161(c) [Results indicating an adulterated specimen] would be added to establish criteria for HHS-certified laboratories to apply in determining whether to report to a licensee's or other entity's MRO that a specimen is adulterated. Proposed §26.161(c)(1)–(c)(7) would specify results from initial and confirmatory validity testing that would indicate that a specimen is adulterated. The proposed paragraphs would also specify the appropriate testing devices and instruments to be used for initial and confirmatory validity tests. In general, the proposed paragraphs would require the HHS-certified laboratory to report to the MRO that a urine specimen is adulterated if it meets any one of the following criteria: (1) it is confirmed to contain a substance that should not be present at all in normal human urine; (2) it is confirmed to contain a substance which, although it could be present in normal human urine, is found to be at a concentration that appears to be completely inconsistent with human physiology; or (3) it presents an acid/base balance (pH) that appears to be inconsistent with human life. The proposed paragraphs would address several substances that some donors have used to try to defeat drug tests through "in vitro" contamination (i.e., adding the substance to a urine specimen). These adulterants include substances that create a urine pH inconsistent with human life, oxidizing adulterants, chromium (VI), halogens, glutaraldehyde, pyridine, and surfactants. These substances, when either placed into an already voided urine or used in place of a urine specimen, generally either attempt to defeat the chemistry of the test or destroy a drug that is present. The NRC recognizes that this list will be updated and/or modified as new substances and formulas are introduced, and as the HHS-certified laboratories develop methods to detect them. Proposed §26.131(c)(8) would recognize that new adulterants will be found and, therefore, would require HHS-certified laboratories to use appropriate testing

methods when conducting initial and confirmatory testing for new adulterants for which cutoff levels and criteria have not yet been established.

Proposed §26.161(d) [Results indicating a substituted specimen] and (e) [Results indicating a dilute specimen] would establish cutoff levels and criteria for a determination by the laboratory that a specimen has been substituted or is dilute, respectively. In proposed §26.161(d), the HHS-certified laboratory would report to the MRO that a specimen is substituted if it contains less than 2 mg/dL of creatinine and the specific gravity is less than or equal to 1.001 or equal to or greater than 1.020. These low creatinine concentrations combined with the highly skewed specific gravity values indicate that the specimen is not human urine. In proposed §26.161(e), the HHS-certified laboratory would be required to report to the MRO that a specimen is dilute if it contains 2–20 mg/dL of creatinine and has a specific gravity of less than or equal to 1.001 or equal to or greater than 1.020.

Proposed §26.161(f)(1)–(f)(10) [Results indicating an invalid specimen] would be added to establish the criteria that HHS-certified laboratories would apply when determining that a specimen is invalid. In 1998, HHS established criteria for what were termed "unsuitable" specimens (Program Document 35, September 28, 1998). An unsuitable specimen was defined as one that contained an interfering substance but the laboratory could not determine the nature of the substance with scientific certainty. In these circumstances, the laboratory could not achieve a "valid" test result. The HHS recognized that in some cases, an interfering substance could be a legitimately ingested medication (some non-steroidal anti-inflammatories have been known to interfere with the chemistry of some of the initial tests). However, it was also recognized that many of these problem specimens actually contained an adulterant which the laboratory could not specifically identify with scientific certainty (the requirement for reporting a specimen as adulterated). Therefore, the HHS adopted the term, “invalid

specimen," to mean that the laboratory has determined that valid test results cannot be obtained from a specimen or an unknown substance interfered with the confirmatory test. The proposed rule would adopt the term, "invalid specimen," with the same meaning.

Proposed §26.161(g) [Additional testing by a second laboratory] would be added to address circumstances in which an HHS-certified laboratory suspects that a specimen is adulterated but cannot identify the adulterant. The proposed paragraph would permit the laboratory to transfer the specimen to a second HHS-certified laboratory for additional testing, if the first HHS-certified laboratory cannot identify a possible adulterant in the specimen using their standard testing technologies and the licensee's or other entity's MRO concurs with the additional testing. Personnel at the first HHS-certified laboratory would consult with the licensee's or other entity's MRO to determine whether to transfer the specimen to a second laboratory for additional testing.

Proposed §26.161(h) [More stringent validity test cutoff levels are prohibited] would be added to prohibit licensees and other entities from requiring an HHS-certified laboratory to apply validity testing cutoff levels and criteria that are more stringent than those specified in this proposed section. Because validity testing is complex and the methods for testing are relatively new, the proposed rule would not permit an FFD program to establish more stringent cutoff levels for validity testing. The proposed prohibition would be necessary to decrease the risk of obtaining false non-negative test results and ensure that donors are not subject to sanctions on the basis of inaccurate test results.

Section 26.163 Cutoff levels for drugs and drug metabolites

Proposed §26.163 [Cutoff levels for drugs and drug metabolites] would group together in one section, for organizational clarity, the proposed requirements for conducting initial and

confirmatory tests for drugs and drug metabolites at HHS-certified laboratories. The proposed section would also update requirements related to cutoff levels for drugs and drug metabolites in the current rule to meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.163(a) [Initial drug testing] would amend current Section 2.7(e) in Appendix A to Part 26. When determining whether to report to the MRO that a specimen is positive for drug(s) or drug metabolite(s), proposed §26.163(a)(1) would require HHS-certified laboratories to apply the same cutoff levels that licensee testing facilities would be required to use in proposed §26.133 [Cutoff levels for drugs and drug metabolites], except if the FFD program specifies more stringent cutoff levels or the specimen is dilute, as discussed further with respect to proposed §26.163(a)(2). The proposed paragraph would reiterate the current permission for licensees and other entities to establish lower cutoff levels. In addition, proposed §26.163(a)(1) would decrease the initial test cutoff level for marijuana metabolites from 100 nanograms (ng) per milliliter (mL) to 50 ng/mL and increase the initial test cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL for the reasons discussed with respect to proposed §26.133. The proposed changes would be consistent with the HHS cutoff levels for the same substances.

Proposed §26.163(a)(2) would be added to establish requirements and criteria for the initial drug testing of any specimen that confirmatory validity testing indicates is dilute. Although there are many legitimate reasons that a donor may provide a urine specimen that is dilute, dilution is also a method used to subvert the testing process. Dilution of a specimen decreases the concentration of any drugs or drug metabolites in the specimen. Dilution may decrease the concentration sufficiently that applying the cutoff levels specified in this part, or a licensee's or other entity's more stringent cutoff levels, would provide false negative drug test results.

Therefore, the proposed rule would add special testing procedures and criteria for determining which dilute specimens must be subject to confirmatory drug testing.

The proposed paragraph would require HHS-certified laboratories to conduct initial drug testing of dilute specimens using FDA-approved analytical kits that have the lowest concentration levels available for the initial testing technologies used. If responses from the dilute specimen on the initial drug test are within 50 percent of the established cutoff level for the drug or drug metabolite, the proposed rule would require the HHS-certified laboratory to report this result to the licensee's or other entity's MRO. If the FFD program's policy specifies this requirement, the proposed rule would permit the MRO to direct the HHS-certified laboratory to test the specimen at the confirmatory assay's LOD for that drug or drug class and report the results to the MRO. This special processing of dilute specimens would increase the likelihood that any drugs and drug metabolites in the specimen would be detected. Therefore, this proposed requirement would meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs, by increasing the likelihood that testing of dilute specimens would reveal drug use, if the donor had engaged in substance abuse.

As discussed with respect to proposed §26.133 [Cutoff levels for drugs and drug metabolites], the proposed rule would eliminate the requirement in the last sentence of current Section 2.7(e)(1) for HHS-certified laboratories to report drug test results for both the cutoff levels in the rule and any more stringent cutoff levels that the licensee or other entity may establish. The basis for the current requirement to report test results for the cutoff levels specified in this part, when the licensee is using more stringent cutoff levels, was a means by which the NRC monitored implementation of the permission to use more stringent cutoff levels. The proposed rule would eliminate this requirement, because proposed §26.31(d)(3)(iii)(C) would require a qualified forensic toxicologist to certify the scientific and technical validity of any

testing at lower cutoff levels. Therefore, the current reporting requirement is no longer needed to assure laboratory performance in this area. Eliminating this requirement would meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

The proposed rule would also eliminate current Section 2.7(e)(2), which states that the list of substances and cutoff levels contained in Appendix A to Part 26 are subject to change by the NRC. At the time the current rule was published, the NRC expected to be able to amend the list of substances and cutoff levels in Appendix A to Part 26 without additional rulemaking. However, the NRC has determined that rulemaking is required to make such changes. Therefore, the proposed rule would delete this paragraph because it is unnecessary.

The proposed rule would replace current Section 2.7(f) in Appendix A to Part 26, which establishes cutoff levels and requirements related to confirmatory testing for drugs and drug metabolites at the HHS-certified laboratory, with proposed §26.163(b) [Confirmatory drug testing]. The proposed rule would also make a number of changes to the current paragraph.

The proposed rule would move current Section 2.7(f)(1) in Appendix A to Part 26 to proposed §26.169(b). Current Section 2.7(f)(1) requires the HHS-certified laboratory to report to the MRO that test results are negative for any specimens that yield negative test results when they are subjected to confirmatory testing. This requirement would be moved to proposed §26.169(b) for organizational clarity because proposed §26.169 [Reporting results] addresses the topic of reporting test results by the HHS-certified laboratory to the MRO.

The proposed rule would also eliminate the requirement in current Section 2.7(f)(1) in Appendix A to Part 26 that the laboratory must conduct confirmatory testing using both the maximum cutoff values established in Part 26 as well as any more stringent cutoff levels adopted by the licensee's or other entity's FFD program. The current requirement to conduct

testing for the cutoff levels specified in this part, when the licensee is using more stringent cutoff levels, was a means by which the NRC monitored implementation of the permission to use more stringent cutoff levels. The proposed rule would eliminate this requirement, because proposed §26.31(d)(3)(iii)(C) would require a qualified forensic toxicologist to certify the scientific and technical validity of any testing at lower cutoff levels. Therefore, the requirement to test at both cutoff levels would no longer be needed to assure laboratory performance in this area.

For organizational clarity, the requirement in the first sentence of current Section 2.7(f)(2) in Appendix A to Part 26 that the laboratory must use GC/MS techniques for confirmatory testing would be moved to proposed §26.167(e)(1) [Quality control requirements for performing confirmatory drug tests], which would establish quality control requirements for conducting confirmatory drug tests.

The proposed rule would eliminate current Section 2.7(f)(3) in Appendix A to Part 26, which requires HHS-certified laboratories to use GC analysis of blood specimens in testing for alcohol, and the confirmatory alcohol cutoff level in current Section 2.7(f)(1) in Appendix A to Part 26. These provisions would be eliminated because the proposed rule would no longer permit donors to request confirmatory testing of a blood specimen for alcohol, as discussed with respect to proposed §26.83(a).

In addition, the proposed rule would eliminate current Section 2.7(f)(4) in Appendix A to Part 26 for the same reasons discussed with respect to current Section 2.7(e)(2) in Appendix A to Part 26.

Proposed §26.163(b)(1) would amend several of the cutoff levels in current Section 2.7(f)(1) in Appendix A to Part 26 that the HHS-certified laboratory uses to determine that a confirmatory drug test result is positive. The proposed rule would increase the

confirmatory test cutoff levels for morphine and codeine to 2,000 ng/mL. This proposed change in the cutoff levels for opiate metabolites would substantially reduce the number of positive opiate test results that are reported to MROs by HHS-certified laboratories that MROs ultimately verify as negative and would be consistent with the opiate cutoff levels contained in the HHS Guidelines.

Proposed §26.163(b)(1) would also amend two of the testing procedures in current Section 2.7(f) in Appendix A to Part 26. The proposed rule would amend Section 2.7(f)(5) in Appendix A to Part 26, which requires the laboratory to test for 6-acetylmorphine (6-AM) if a specimen tests positive for opiates on the initial drug test. The proposed rule would require the HHS-certified laboratory to test for 6-AM, if test results for morphine are at or above the 2,000 ng/mL opiate cutoff levels, and establish a cutoff level of 10 ng/mL for determining that a specimen is positive for 6-AM. In addition, proposed §26.163(b)(1) would add a requirement that a specimen must contain amphetamine at a concentration equal to or greater than 200 ng/mL in order for the HHS-certified laboratory to report to the MRO that the specimen has yielded a positive test result for methamphetamine. These proposed changes would be made for consistency with the related provisions in the HHS Guidelines.

Proposed §26.163(b)(1) would update the terminology used in current Section 2.7(f)(1) in Appendix A to Part 26. As discussed with respect to proposed §26.5 [Definitions], the proposed paragraph would replace the term, “presumptive positive,” with the phrase, “positive on an initial drug test,” to increase clarity in the language of the rule.

Proposed §26.163(b)(2) would amend the second sentence of current Section 2.7(f) in Appendix A to Part 26, which requires the HHS-certified laboratory to document drug and drug metabolite concentrations that exceed the linear region of the standard curve in the laboratory record. The proposed rule would replace the current sentence with a new paragraph that

incorporates the related provision from the HHS Guidelines. The HHS Guidelines permit the laboratory to dilute an aliquot of the specimen to obtain an accurate quantitative result when the concentration is above the upper limit of the linear range. This proposed change would be made to meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.165 Testing split specimens and retesting single specimens

A new §26.165 [Split specimens] would reorganize and amend the requirements currently found in §26.24(f), and Section 2.7(i) and (j) in Appendix A to Part 26 that are related to testing split specimens and retesting specimens at HHS-certified laboratories. These requirements would be presented together in a single section to make them easier to locate in the proposed rule for organizational clarity. The proposed section would also add several new requirements.

Proposed §26.165(a) [Split specimens] would combine and amend current §26.24(f) and Section 2.7(j) in Appendix A to Part 26, which establish requirements for HHS-certified laboratories when testing split specimens. The proposed paragraph would use the terms, “Bottle A” and “Bottle B,” to refer to the primary and split specimens, respectively, for consistency with the updated terminology used throughout the proposed rule. The proposed paragraph would also require specimen validity testing, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.165(a)(1) would retain the portions of current Section 2.7(j) in Appendix A to Part 26 that require the HHS-certified laboratory to analyze the primary specimen of a split specimen. The current requirements that relate to licensee testing facilities would be moved to

§26.135 [Split specimens] in proposed Subpart F [Licensee Testing Facilities] for organizational clarity. The proposed paragraph would retain the requirement that the primary specimen (Bottle A) must be subject to initial testing by the HHS-certified laboratory, and confirmatory testing, if the specimen yields non-negative results from initial testing. The proposed paragraph would specify that the HHS-certified laboratory must conduct validity tests on the specimen contained in Bottle A, as well as drug tests, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.165(a)(2) would retain the portion of the second sentence of current §26.24(f) that requires the HHS-certified laboratory to perform initial and confirmatory tests, if required, on the specimen in Bottle A if any initial test results from a licensee testing facility are non-negative. This requirement would be moved to the proposed section for organizational clarity. In addition, the term, “positive,” in the current sentence would be replaced with the term, “non-negative,” to indicate that the HHS-certified laboratory must conduct confirmatory testing of any specimens that yield non-negative initial validity or drug test results at the licensee testing facility, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.165(a)(3) would retain the permission in the second sentence of current Section 2.7(j) in Appendix A to Part 26 for licensees and other entities to retain custody of the split specimen in Bottle B or forward it with Bottle A to the HHS-certified laboratory for storage until testing of Bottle A is completed. The proposed paragraph would also retain the current permission for the specimen in Bottle B to be discarded if test results from the HHS-certified laboratory are negative.

Proposed §26.165(a)(4) would amend the requirements in current Section 2.7(j) in Appendix A to Part 26, as they relate to donor requests to test the specimen in Bottle B. The

proposed paragraph would add non-negative validity test results as a basis for a donor request for testing the specimen in Bottle B, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The proposed paragraph would also add a requirement that the donor must request testing of the Bottle B specimen within 3 business days after notification by the MRO that the specimen in Bottle A has yielded non-negative test results. Since 1994, the HHS Guidelines have allowed up to 72 hours for a donor to make this request, so the proposed change would increase the consistency of Part 26 with the HHS Guidelines.

The proposed paragraph would also require the donor to provide written permission to the licensee or other entity for testing of the specimen contained in Bottle B and clarify that only the donor may authorize testing of Bottle B. At the public meetings discussed in Section V, stakeholders indicated that the proposed requirement for a written request from donors would impose a substantial logistical burden on donors who may not be working on site when contacted by the MRO. However, the NRC believes that the proposed requirement is necessary to ensure that the donor's right to privacy and control of the specimen is protected, consistent with Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Proposed §26.165(a)(5) would require the HHS-certified laboratory to forward Bottle B to a second HHS-certified laboratory for testing within one business day of the donor's request for testing. The proposed paragraph would eliminate the requirement in the fourth sentence of current Section 2.7(j) in Appendix A to Part 26, which requires that the split specimen must be forwarded to another HHS-certified laboratory for testing on the same day of the donor request. The proposed change would respond to stakeholder feedback during the public meetings discussed in Section V. The stakeholders reported that implementing the same-day

requirement has often been difficult for a number of reasons, including, for example, communication delays among donors, MROs, the HHS-certified laboratories, and FFD program personnel, particularly on weekends and holidays, and the time required to identify a second laboratory with the appropriate capability to test the split specimen, depending upon the nature of the non-negative test result. The proposed change would alleviate some these types of logistical difficulties (e.g., logistical problems associated with weekends and holidays) while continuing to provide the donor with timely test results. Therefore, this proposed change would meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

Proposed §26.165(a)(6) would retain the last sentence of current Section 2.7(j) in Appendix A to Part 26, which requires the second HHS-certified laboratory to provide quantitative test results from Bottle B to the MRO, who would provide them to the donor. The proposed paragraph would adopt the simpler language from the related provision in the HHS Guidelines, consistent with Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

Proposed §26.165(b) [Donor request to MRO for a retest of a single specimen] would be added to permit donors to request retesting of an aliquot from a single specimen, if the FFD program does not follow split specimen procedures. The proposed paragraph would assure that donors who are subject to a program that does not follow split specimen procedures have the right to request additional testing. The proposed change would be consistent with related provisions in the HHS Guidelines. However, in order to have sufficient urine to support retesting, the proposed paragraph would apply only if the donor had submitted a specimen of 30 mL or more. Specimens that the HHS-certified laboratory determines to be invalid would not be eligible for retesting because of the risk of damage to laboratory equipment that some invalid

specimens may pose and because retesting the specimen would not provide useful information. The proposed procedures for requesting and conducting the retest of a single specimen would be consistent with those for requesting and conducting tests on the specimen in Bottle B of a split specimen.

Proposed §26.165(c) [Retesting a specimen for drugs] would amend current Section 2.7(i) in Appendix A to Part 26, which specifies that retesting of a specimen is not subject to cutoff requirements. The proposed paragraph would update and expand current requirements for retesting a single specimen or Bottle B of a split specimen for drugs and drug metabolites to be consistent with the related provisions in the HHS Guidelines, as follows:

Proposed §26.165(c)(1) would be added to require the second HHS-certified laboratory to use the laboratory's standard confirmatory test for the drug or drug metabolite for which the specimen tested positive at the first laboratory. Initial tests, and tests for other drugs or drug metabolites, would not be performed, consistent with the related requirements in the HHS Guidelines.

Proposed §26.165(c)(2) would amend current Section 2.7(i) in Appendix A to Part 26, which specifies that retesting of a specimen is not subject to cutoff requirements. The proposed paragraph would retain the requirement for the second HHS-certified laboratory to provide data sufficient to confirm the presence of the drug(s) or drug metabolite(s) and add permission to test the specimen down to the assay's LOD. Adding permission to test down to the assay's LOD would be consistent with the related requirement in the HHS Guidelines and would ensure that the second laboratory's testing is as sensitive to the presence of the drug(s) or drug metabolite(s) as scientifically and legally defensible.

Proposed §26.165(c)(3) would be added to require the second laboratory to attempt to determine the reason if retesting fails to confirm the presence of the drug(s) or drug

metabolite(s) that was identified by the first HHS-certified laboratory. The proposed paragraph would require the second laboratory to conduct specimen validity testing if the second laboratory fails to reconfirm the first laboratory's findings, consistent with the related requirements in the HHS Guidelines

Proposed §26.165(c)(4) would retain the requirement in the last sentence of current Section 2.7(j) in Appendix A to Part 26 that requires the second laboratory to report the test results to the MRO. The proposed rule would extend this requirement to retesting of a single specimen, consistent with the explicit permission added in proposed §26.165(b) for a donor to request retesting of a single specimen, if the FFD program does not follow split specimen procedures. The proposed requirement would be consistent with the related requirements in the HHS Guidelines.

Proposed §26.165(d) [Retesting a specimen for adulterants] and (e) [Retesting a specimen for substitution] would be added to incorporate related requirements in the HHS Guidelines for performing retests for adulterants and substituted specimens at a second HHS-certified laboratory. Retesting for adulterants would be limited to conducting confirmatory testing only for the adulterant(s) identified by the first laboratory. Retesting for specimen substitution would be limited to conducting confirmatory testing only for creatinine and specific gravity. These proposed limitations would be consistent with limitations on retesting specimens for drugs and drug metabolites.

Proposed §26.165(f) [Management actions and sanctions] would be added to specify the actions that licensees and other entities must take when a donor requests a retest of a single specimen or testing of Bottle B of a split specimen. The proposed paragraph would respond to stakeholder comments at the public meetings discussed in Section V. The stakeholders noted that the current rule does not address required management actions when

an individual has had a confirmed non-negative test result and requests a retest of a single specimen or Bottle B of a split specimen. Therefore, the proposed paragraph would be added to establish such requirements.

Proposed §26.165(f)(1) would be added to address circumstances in which the MRO has confirmed a non-negative test result from the HHS-certified laboratory as a violation of the licensee's or other entity's FFD policy and the donor requests a retest of a single specimen or testing of the specimen in Bottle B. The proposed paragraph would require the licensee or other entity to take the same actions in response to the confirmed non-negative test result(s) from the first HHS-certified laboratory as the actions that licensees and other entities would be permitted to take under proposed §26.75(i) in response to a positive drug test result for marijuana or cocaine from initial testing at a licensee testing facility. That is, proposed §26.165(f) would require the licensee or other entity to administratively withdraw the donor's authorization until the test results from the second HHS-certified laboratory have been reported to and reviewed by the MRO. If the test results from the second laboratory confirm any non-negative test results from the first HHS-certified laboratory, the proposed paragraph would require the licensee or other entity to impose the appropriate sanctions that are specified in proposed Subpart D [Management actions and sanctions] for the non-negative test results that were confirmed by the second laboratory. If the test results from the second laboratory do not confirm any non-negative test results, the proposed rule would (1) prohibit the licensee or other entity from imposing any sanctions on the individual; (2) require the licensee or other entity to eliminate any records of the first confirmed non-negative test results; and (3) require the licensee or other entity to inform the donor, in writing, that the records have been expunged and that he or she need not disclose the temporary administrative action to any other licensee or entity. These proposed requirements would protect public health and safety and the common

defense and security by ensuring that an individual whose fitness for duty is questionable does not perform any duties or have the types of access that require the individual to be subject to this part, while protecting the donor's right to due process.

Proposed §26.165(f)(2) would be added to address the unlikely circumstances in which a donor requests retesting of a single specimen or testing Bottle B of a split specimen, but the testing cannot be performed because the single specimen or Bottle B is no longer available due to causes that are outside of the donor's control. These causes could include, for example, an insufficient quantity of urine in the single specimen to permit retesting, either Bottle B or the original single specimen is lost in transit to the second HHS-certified laboratory, or Bottle B has been misplaced.

The proposed paragraph would require the MRO to cancel the original test result, prohibit the licensee or other entity from imposing any sanctions on the donor, and require the licensee or other entity to ensure that any records are expunged that could link the donor to the original non-negative test result and the administrative action required under proposed §26.165(f)(1). The proposed paragraph would require the licensee or other entity to document that the test was performed and cancelled, if the original specimen was collected for random, for-cause, or post-event testing. However, the MRO would direct the licensee or other entity to collect another specimen from the donor as soon as reasonably practical, if the original specimen was collected for pre-access or followup testing. The proposed paragraph would not require a second collection for a random test because a second collection could not satisfy the requirements for random testing [i.e., the donor would not have the same probability of being selected for testing as all other donors who are subject to the FFD program, as required under proposed §26.31(c)(iv)]. The proposed rule also would not require a second collection when the original test was conducted for cause or post event because test results from a second

collection could not accurately measure the presence of drugs or drug metabolites under the conditions that required the original collection due to the passage of time. The proposed paragraph would require a second collection as soon as reasonably practical for pre-access and followup testing because other provisions of the proposed regulation (see proposed Subpart C [Granting and Maintaining Authorization]) require negative test results in order for the licensee or other entity to grant or maintain the donor's authorization.

The last sentence of proposed §26.165(f)(2) would require the licensee or other entity to impose the appropriate sanctions, as specified in proposed Subpart D [Management actions and sanctions], if the results of testing the specimen from a second collection are non-negative and confirmed by the MRO to be an FFD policy violation. However, the proposed rule would prohibit the licensee or other entity from considering the results of testing the original specimen when imposing sanctions because the donor was (inadvertently) denied his or her right to due process in this case.

The new requirements in proposed §26.165(f) would be generally consistent with related requirements in the HHS Guidelines. The differences from the HHS Guidelines' requirements in the proposed rule would be variations in the terminology used to adapt the language for the NRC's purposes and the addition of cross-references to other portions of the proposed rule.

Section 26.167 Quality assurance and quality control

Proposed §26.167 [Quality assurance and quality control] would update current Section 2.8 in Appendix A to Part 26, which establishes quality assurance and quality control requirements for drug testing at HHS-certified laboratories. The proposed section would provide more detailed requirements for the quality assurance and quality control programs of HHS-certified laboratories for consistency with related provisions in the HHS Guidelines, and

add new requirements for validity testing, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.167(a) [Quality assurance program] would amend and combine current Section 2.8(a) and the last two sentences of Section 2.8(d) in Appendix A to Part 26, which require HHS-certified laboratories and licensee testing facilities to have quality assurance programs. For increased clarity in the language of the rule, the proposed rule would replace the term, “specimen acquisition,” with the term, “specimen accessioning,” in the first sentence of current Section 2.8(a), which is the more accurate term. The proposed rule would also add a requirement for the quality assurance program to encompass the certification of calibrators and controls to ensure that calibrators and controls are accurate, which would be consistent with the related provision in the HHS Guidelines.

In addition, the proposed rule would move to proposed §26.167(a) and amend the requirements in the last two sentences of current Section 2.8(d) in Appendix A to Part 26, which require that the linearity and precision of testing methods used must be periodically documented as well as the procedures to ensure that carryover does not contaminate a donor’s specimen. The proposed rule would update these requirements for consistency with the HHS Guidelines and require that (1) the performance characteristics (e.g., accuracy, precision, LOD, limit of quantitation (LOQ), specificity) for each test must be validated and documented; (2) validation of procedures must document that carryover does not affect the donor's specimen results, and (3) the laboratory must periodically re-verify the analytical procedures. These requirements would be moved to proposed §26.167(a) for organizational clarity because they are aspects of the laboratory’s quality assurance program.

The requirements in current Section 2.8(a) in Appendix A to Part 26 that apply to licensee testing facilities would be moved to §26.137(a) [Quality assurance program] in proposed Subpart F [Licensee Testing Facilities] for organizational clarity. The second sentence of current 2.8(a) would be retained in proposed §26.167(a).

The quality control requirements for initial tests at licensee testing facilities in current Section 2.8(b) in Appendix A to Part 26 would be relocated to §26.137 [Quality assurance and quality control] in proposed Subpart F [Licensee Testing Facilities]. The proposed change would be made for organizational clarity.

Proposed §26.167(b) [Calibrators and controls required] would retain the portions of current Section 2.8(c) and (d) in Appendix A to Part 26 that require HHS-certified laboratories to use appropriate calibrators and controls for initial and confirmatory drug testing. The proposed rule would add a requirement to include appropriate calibrators and controls for initial and confirmatory validity testing, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The more detailed requirements for calibrators and controls in current Section 2.8(c) and (d) would be amended and presented in this section of the proposed rule in separate paragraphs that address each type of test to be performed by the HHS-certified laboratory. The proposed changes would be made for increased consistency with the HHS Guidelines and to improve the organizational clarity of the proposed rule.

Proposed §26.167(c) [Quality control requirements for performing initial and confirmatory validity tests] would be added to establish quality control requirements for performing initial and confirmatory validity tests at an HHS-certified laboratory. The quality control requirements for validity tests in this proposed paragraph would incorporate the related provisions of the HHS Guidelines.

Proposed §26.167(c)(1) [Requirements for performing creatinine tests] would be added to require HHS-certified laboratories to measure creatinine concentration to 1 decimal place on initial and confirmatory creatinine tests and establish requirements for the quality control samples to be used in initial and confirmatory tests for creatinine concentration.

Proposed §26.167(c)(2) [Requirements for performing specific gravity tests] would be added to establish the required characteristics of the refractometers used by HHS-certified laboratories to measure specific gravity and the characteristics of the quality control samples to be used for initial and confirmatory tests for a specimen's specific gravity.

Proposed §26.167(c)(3) [Requirements for performing pH tests] would be added to establish quality control requirements for performing initial and confirmatory pH tests. Proposed §26.167(c)(3)(i)–(c)(3)(v) would specify the required calibrators and controls for pH testing, based upon the type of testing instrument used and whether a pH validity screening test has been performed.

The proposed rule would add three additional paragraphs related to quality control of initial and confirmatory validity testing: proposed §26.167(c)(4) [Requirements for performing oxidizing adulterant tests], proposed §26.167(c)(5) [Requirements for performing nitrite tests], and proposed §26.167(c)(6) [Requirements for performing "other" adulterant tests]. The proposed paragraphs would establish quality control requirements for performing initial and confirmatory tests for oxidizing adulterants, among which nitrites are one example, and for "other" adulterants.

Proposed §26.167(d) [Quality control requirements for initial drug tests] would amend and combine portions of current Sections 2.7(d) and (e)(1), and 2.8(c) in Appendix A to Part 26, which establish quality control requirements for performing initial tests for drugs and drug metabolites at HHS-certified laboratories. The proposed paragraph would group together the

current requirements that are dispersed throughout the rule to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule. In addition, the proposed rule would amend a number of the current requirements, as follows:

Proposed §26.167(d)(1) would amend the first sentence of current Section 2.7(e)(1) in Appendix A to Part 26 but retain the intent of the current provision as it applies to HHS-certified laboratories. The current and proposed paragraphs require laboratories to use only immunoassay tests that meet the requirements of the Food and Drug Administration for commercial distribution. The requirements in the current paragraph related to initial drug testing at licensee testing facilities would be moved to §26.137(e)(1) of proposed Subpart F [Licensee Testing Facilities] to improve organizational clarity in the rule.

Proposed §26.167(d)(2) would permit HHS-certified laboratories to conduct multiple tests of a single specimen for the same drug or drug class. The requirements in this paragraph would be consistent with a similar provision in the HHS Guidelines and would be added to meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.167(d)(3)(i)–(d)(3)(vi) would update current Section 2.8(c) in Appendix A to Part 26, which requires HHS-certified laboratories to include quality control samples in each analytical run of specimens for initial drug testing. Proposed §26.167(d)(3)(i)–(d)(3)(vi) would specify the number and characteristics of the quality control samples to be included in each analytical run of specimens. These proposed requirements would be the same as those contained in proposed §26.137(e)(6) and (e)(7) for initial drug tests at licensee testing facilities and would be added for consistency with the related provisions in the HHS Guidelines.

Proposed §26.167(e) [Quality control requirements for performing confirmatory drug tests] would update and combine portions of current Sections 2.7(f)(2) and 2.8(d) in Appendix A

to Part 26, which address quality control requirements for performing confirmatory drug tests. In general, the proposed changes to the current requirements would be made for organizational clarity in the proposed rule and to incorporate the related provisions in the HHS Guidelines.

Proposed §26.167(e)(1) would amend current Section 2.7(f)(2) in Appendix A to Part 26, which requires that confirmatory drug tests must be performed using gas chromatography/mass spectrometry (GC/MS). The proposed paragraph would permit HHS-certified laboratories to use other techniques for confirmatory drug testing that the HHS Guidelines approve for use in Federal workplace drug testing programs.

Proposed §26.167(e)(2)(i)–(e)(2)(iv) would amend the requirements for quality control samples in current Section 2.8(d) in Appendix A to Part 26. Proposed §26.167(e)(2)(i) and (e)(2)(ii) would retain the current requirements for laboratories to include blank samples and samples that contain known standards in each analytical run. The proposed requirements would adopt the simpler language from the related provisions in the HHS Guidelines to improve clarity in the language of the rule. For consistency with the related requirements in the HHS Guidelines, the proposed paragraph would provide more detailed requirements for “positive controls with the drug or metabolite at or near the threshold” in current Section 2.8(d)(1) in Appendix A to Part 26. The proposed rule would require, in proposed §26.167(e)(2)(iii), at least one control fortified with a drug or drug metabolite targeted at 25 percent above the cutoff and, in proposed §26.167(e)(2)(iv), at least one calibrator or control that is targeted at or below 40 percent of the cutoff.

Proposed §26.167(f) [Blind performance testing] would amend current Section 2.8(e) in Appendix A to Part 26, which establishes requirements for licensees and other entities to conduct blind performance testing of HHS-certified laboratories, as follows:

Proposed §26.167(f)(1) would amend the portion of current Section 2.8(e)(2) in Appendix A to Part 26 that establishes the percentages and numbers of blind performance test samples that licensees and other entities must submit to the HHS-certified laboratory during the first 90 days of any initial contract with the HHS-certified laboratory. The proposed paragraph would decrease the percentage of blind performance test samples that licensees and other entities would submit to the HHS-certified laboratory during the initial 90-day period of any contract (not including rewritten or renewed contracts). Specifically, the proposed rule would reduce the percentage from 50 percent to 20 percent of the total number of specimens submitted in the 90-day period, up to a maximum of 100 blind samples, rather than a maximum of 500 samples as specified in the current rule. This proposed decrease in the blind performance testing rate would increase the consistency of Part 26 requirements with the related provisions in the HHS Guidelines. In addition, since the NRC published the current rule, the number and size of Federal agencies who conduct drug testing has substantially increased, and these agencies are also required to submit blind performance test samples under the HHS Guidelines. As a result, the burden on Part 26 programs to conduct performance tests of the HHS-certified laboratories may be reduced without affecting the likelihood that errors in testing will be detected.

The proposed rule would also add a requirement for licensees and other entities to submit a minimum of 30 blind performance test specimens in the 90-day period. This proposed minimum would be established to address Part 26 programs who submit only a small number of specimens to HHS-certified laboratories for testing each quarter. For example, for a very small program, 20 percent of the number of specimens submitted in the 90-day period could be less than one blind performance test sample. Establishing a minimum number of samples would

provide assurance that the HHS-certified laboratories used by these Part 26 programs are providing accurate test results.

Proposed §26.167(f)(2) would amend the portion of current Section 2.8(e)(2) in Appendix A to Part 26 that addresses ongoing blind performance testing after the first 90 days of an initial contract with an HHS-certified laboratory. The proposed rule would decrease the rate at which licensees and other entities must submit blind performance test samples to an HHS-certified laboratory in each quarter after the initial 90-day period from 10 percent in the current rule to 1 percent, or a total of 10 samples, whichever is greater. The proposed rule would also decrease the maximum number of samples to be submitted per quarter from 250 to 100 samples. The rationale for these proposed changes would be the same as discussed with respect to proposed §26.167(f)(1).

Proposed §26.167(f)(3) would decrease the proportion of spiked blind samples that licensees and other entities would submit each quarter from 20 percent in Section 2.8(e)(3) in Appendix A to Part 26 to 15 percent. The proposed rule would retain the current requirement that samples must be spiked with only the drugs that are included in the licensee's or other entity's panel of drugs. The proposed rule would add a requirement that the spiked samples must be spiked to between 60–80 percent of the initial cutoff levels used by the licensee or other entity to be consistent with related requirements in the HHS Guidelines. In addition, the proposed rule would add a requirement for licensees and other entities to submit samples that meet the criteria for adulteration, dilution, and substitution, in order to challenge the laboratory's validity testing. Licensees and other entities would be required to submit blind samples each quarter that are appropriately adulterated, diluted, or substituted, in the amount of 5 percent of the specimens submitted that quarter or at least 3 samples per quarter (one each that is adulterated, diluted, or substituted), whichever is greater. This proposed change would be

made for consistency with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i), and would be necessary to challenge the accuracy of the HHS-certified laboratory's specimen validity testing.

Proposed §26.167(f)(4) would retain current Section 2.8(e)(3) in Appendix A to Part 26, which requires that 80 percent of the blind samples submitted by the licensee or other entity each quarter to the HHS-certified laboratory must be "blank" (i.e., certified to contain no drugs or drug metabolites).

Proposed §26.167(f)(5) would be added to establish detailed requirements for the blind performance test samples that licensees and other entities must submit to the HHS-certified laboratories. The proposed rule would require the supplier of the blind samples to certify and provide an expiration date for each sample. Proposed §26.167(f)(i) and (f)(ii) would specify the characteristics of the samples that licensees and other entities would be required to use to challenge the HHS-certified laboratory's drug and validity testing, respectively. The proposed quality control requirements would be necessary to ensure the effectiveness of the blind performance testing process and would incorporate the related requirements in the HHS Guidelines.

Proposed §26.167(g) [Errors in testing] would amend current Section 2.8(e)(4)–(e)(6) in Appendix A to Part 26, which establishes requirements for licensees, other entities, and HHS-certified laboratories related to unsatisfactory performance, including false positive and false negative test results, by the HHS-certified laboratory. The proposed paragraph would require the licensee or other entity to ensure that the HHS-certified laboratory investigates any conditions that may adversely reflect on the testing process. Notably, the proposed rule would no longer require the licensee to perform the investigation, but rather to "ensure" that the laboratory completes an investigation. This change is proposed because licensees and other

entities do not typically retain personnel with the expertise required to investigate the complex technologies and processes involved in testing at the HHS-certified laboratories. The requirement for documentation of the investigation, which currently appears in Section 2.8(e)(4) in Appendix A to Part 26, would be moved to §26.215(b)(8) in proposed Subpart J [Recordkeeping and Reporting Requirements] for organizational clarity.

Proposed §26.167(g)(1) would explicitly state the requirements that are implied in current Section 2.8(e)(4) in Appendix A to Part 26, that the investigation must identify the root cause(s) of any unsatisfactory performance and the HHS-certified laboratory must take corrective actions. The proposed rule would expand these requirements to include the licensee or other entity, as well as the HHS-certified laboratory, depending upon the causes identified and the extent to which the causes are within each entity's control. The proposed requirement would be added to recognize that some testing errors are not attributable to the HHS-certified laboratory.

Proposed §26.167(g)(2) would amend current Section 2.8(e)(5) in Appendix A to Part 26, which requires the licensee to notify the NRC if a false positive error occurs on a blind performance test sample and the error is determined to be administrative. The proposed paragraph would require the licensee or other entity, and the HHS-certified laboratory, to take corrective actions for any false positive errors in blind performance testing, in response to the findings of the investigation that would be required in proposed §26.167(i). The proposed rule would continue to authorize licensees and other entities to require the laboratory to review and re-analyze previously tested specimens, if the investigation indicates that the error could have been systematic. The proposed rule would also delete reference to administrative errors, which appears in current Section 2.8(e)(5), so that any type of errors would fall under the requirements of the proposed paragraph. The reporting requirement in current

Section 2.8(e)(5) would be moved to §26.219(c)(2) in proposed Subpart J [Recordkeeping and Reporting Requirements] for organizational clarity.

Proposed §26.167(g)(3) would amend current Section 2.8(e)(6) in Appendix A to Part 26, which addresses false positive errors resulting from methodological errors by the laboratory. The proposed rule would incorporate reference to validity testing, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as previously discussed with respect to §26.31(d)(3)(i). The proposed rule would also replace the reference to the individual who is responsible for day-to-day management of the laboratory with a requirement for the laboratory's certifying scientist to document the retesting of specimens that may be required under this paragraph. This proposed change would be made for consistency with the related provision of the HHS Guidelines. The proposed paragraph would delete the last sentence of the current paragraph because it addresses the responsibilities of the HHS and is not relevant to the NRC or the licensees and other entities who are subject to Part 26. The proposed paragraph would retain the other provisions of current Section 2.8(e)(6), but adopt the simpler language of the related provision in the HHS Guidelines for increased clarity in the language of the proposed rule.

Proposed §26.167(h) [Accuracy] would retain current Section 2.7(o)(3)(i) in Appendix A to Part 26 with minor editorial revisions. The current paragraph would be relocated to proposed §26.167 because it is related to quality control of the HHS-certified laboratory's drug testing processes. These proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.167(i) [Calibrators and controls] would update current Section 2.7(o)(2) in Appendix A to Part 26. At the time the original paragraph was written, most laboratories prepared their own standards and controls. In the ensuing years, the number and variety of

sources for materials used in performance testing has increased. The proposed paragraph would update current requirements to refer to several of the alternatives, including, but not limited to pure drug reference materials, stock standard solutions from other laboratories, and standard solutions obtained from commercial manufacturers. The proposed requirements in this paragraph incorporate the related requirements in the HHS Guidelines and would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. The labeling requirements in the second sentence of current Section 2.7(o)(2) would be retained.

Section 26.169 Reporting results

Proposed §26.169 [Reporting results] would amend current Section 2.7(g) in Appendix A to Part 26, which contains requirements for HHS-certified laboratories' reporting of test results to the licensee's or other entity's MRO. The proposed rule would update the current requirements for consistency with the HHS Guidelines. In addition, the proposed rule would add requirements for reporting the results of validity testing, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.169(a) would amend current Section 2.7(g)(1) in Appendix A to Part 26, which establishes a time-limit on the HHS-certified laboratory's reporting of test results to the MRO and requirements for the processing and content of the report. The proposed rule would retain the requirement for the laboratory to report results to the MRO within 5 business days of receiving the specimen at the laboratory. Under the proposed rule, the HHS-certified laboratory's "certifying scientist," rather than the laboratory's "responsible individual," would certify the test results. This proposed change would be made for consistency with the updated

term used to refer to this individual, as discussed with respect to proposed §26.155(b). The proposed rule would add a reference to validity test results, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The proposed rule would delete the current prohibition on reporting test results for any specimen in a group of specimens sent to the laboratory by the licensee or other entity until the laboratory completes testing of all of the specimens in the group. The prohibition in the current rule was based upon a concern for maintaining control of specimen identity. However, new technologies for identifying specimens and aliquots (such as bar codes on specimen labels matched to bar codes on aliquots and the associated custody-and-control forms) have reduced the likelihood that specimen identity may be lost, and, therefore, have substantially reduced the need for the requirement in the current rule.

Proposed §26.169(b) would amend current Section 2.7(g)(2) in Appendix A to Part 26, which establishes requirements for the manner in which HHS-certified laboratories and licensee testing facilities must report test results to licensee management. The requirements in the current paragraph that are related to reporting test results from the licensee testing facility would be moved to §26.139(a) of proposed Subpart F [Licensee Testing Facilities] for organizational clarity. The proposed paragraph would delete the current reference to “special processing” and replace it with reference to validity test results, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). In addition, the proposed rule would make minor changes in terminology, such as referring to a “drug or drug metabolite,” rather than a “substance,” for clarity in the rule language.

Proposed §26.169(c) would amend portions of current Section 2.7(f)(2) in Appendix A to Part 26 by deleting the requirement for the HHS-certified laboratory to conduct tests for drugs

and drug metabolites using both the cutoff levels specified in this part and any more stringent cutoff levels specified by the FFD program. Under the proposed rule, if the FFD program specifies cutoff levels that are more stringent than those specified in this part, the laboratory need only conduct testing using those more stringent cutoff levels, and need only report results from those tests to the MRO. This proposed change would be made for the reasons discussed with respect to proposed §26.31(d)(1)(i)(D).

Proposed §26.169(d) would be added to establish requirements for the laboratory's reporting of the results of validity testing. Under the proposed rule, HHS-certified laboratories would be required to report to the MRO quantitative results for any specimen that is found to be dilute, adulterated, or substituted. The MRO would be prohibited from reporting the quantitative validity test results to the licensee or other entity, except as permitted with a signed consent from the donor under proposed §26.37(b). The proposed paragraph also would require the HHS-certified laboratory to contact the licensee's or other entity's MRO when the laboratory concludes that a specimen is invalid, and consult with the MRO to determine whether additional testing by a second HHS-certified laboratory would be useful in being able to report an adulterated or substituted test result. The proposed rule would permit the laboratory's contact with the MRO to occur using electronic means, such as telephone, fax, and email. These proposed reporting requirements would be added for consistency with the related provisions in the HHS Guidelines.

Proposed §26.169(e) would be added to require the HHS-certified laboratory to report more than one test result for a single specimen, if the laboratory obtains more than one non-negative test result from testing of the specimen. This proposed provision would require the laboratory to report any drug-positive test results, as well as any non-negative validity test results from the same specimen. This proposed change is necessary because sanctions for

the different test results would differ under proposed §26.75 [Sanctions]. Reporting multiple test results for a single specimen would be consistent with related requirements in the HHS Guidelines.

Proposed §26.169(f) would update current Section 2.7(g)(3) in Appendix A to Part 26, which permits the MRO routinely to obtain quantitative test results from the HHS-certified laboratory. Specifically, the proposed rule would revise the first sentence of current Section 2.7(g)(3) by stating that the HHS-certified laboratory shall provide quantitative test results to the MRO upon request. The proposed paragraph would clarify the current requirement by stating that the MRO's request may be either a general request covering all such results or a specific case-by-case request. The proposed clarification would be necessary because the current sentence has raised questions from HHS-certified laboratories to the HHS. In addition, the proposed rule would add the third sentence of proposed §26.169(f) to clarify requirements for reporting drug test results when the concentration of a drug, metabolite, or adulterant exceeds the linear range of the standard curve. The proposed rule would also delete the existing reference to test results from blood specimens for the reasons discussed with respect to proposed §26.83(a). Disclosure of quantitative test results to licensees and other entities would continue to be subject to the requirements in proposed §26.37(b). The proposed changes to this paragraph would be consistent with the related provisions in the HHS Guidelines.

Proposed §26.169(g) would require HHS-certified laboratories to report to the MRO quantitative values for confirmatory opiate test results for morphine or codeine that are equal to or greater than 15,000 ng/mL. The proposed rule would add this requirement for consistency with the related provision in the HHS Guidelines and because the MRO would not be required

to perform an assessment for clinical signs of opiate abuse in this instance, as discussed with respect to proposed §26.185(f)(1).

Proposed §26.169(h) would amend current Section 2.7(g)(4) in Appendix A to Part 26, which establishes requirements for the electronic transmission of test results from the HHS-certified laboratory to the MRO. Specifically, the proposed rule would clarify that the licensee or other entity is responsible for assuring the security of data transmissions from the laboratory to the MRO, rather than only the HHS-certified laboratory, as specified in the current requirement. The proposed change would respond to stakeholder comments at the public meetings discussed in Section V. The stakeholders accurately noted that licensees and other entities are responsible to the NRC for ensuring the security of their HHS-certified laboratories' data storage and transmission systems through their contracts with and audits of the laboratories. The proposed revision would more accurately characterize these relationships without changing the intent of the current provision.

Proposed §26.169(i) would update current Section 2.7(g)(5) in Appendix A to Part 26, which establishes requirements for transmitting chain-of-custody documentation with test results to the MRO. The proposed rule would permit HHS-laboratories to use various means to transmit test results to the MRO, including transmittal of a computer-generated electronic report for negative test results. However, for non-negative test results, the proposed rule would require the laboratory to transmit a legible image or copy of the completed custody-and-control form to the MRO. The proposed change would be made for consistency with the related provision in the HHS Guidelines.

Proposed §26.169(j) would further amend current Section 2.7(g)(5) in Appendix A to Part 26. The proposed paragraph would continue to require that the HHS-certified laboratory must retain the original custody-and-control form for any non-negative specimens. However,

the proposed paragraph would assign responsibility for certifying the test results to the laboratory's certifying scientist, rather than to "the individual responsible for day-to-day management of the laboratory or the individual responsible for attesting to the validity of the test reports." The proposed change would be made for consistency with the updated terminology used to refer to this individual in the HHS Guidelines, as discussed with respect to proposed §26.155(b).

Proposed §26.169(k) would combine and amend current Section 2.7(g)(6) and (g)(7) in Appendix A to Part 26, which require the laboratory to submit a monthly statistical summary of drug test results to the licensee or other entity. The proposed rule would reduce the required frequency of the statistical summary report from monthly to annually in order to reduce the burden on licensees, other entities, and their laboratories. The proposed requirement for annual reporting would make the reporting time consistent with the NRC's need for the information as it relates to the NRC's inspection schedule and the annual FFD program performance report that would be required under proposed §26.217 [Fitness-for-duty program performance data], for the reasons discussed with respect to that section. The proposed rule would also delete the existing reference to blood specimens because the option for donors to request blood testing for alcohol would be eliminated from the proposed rule, as discussed with respect to proposed §26.83(a). The proposed rule would also delete the requirement to report drug test results at the cutoff levels specified in this part, if the FFD program uses more stringent cutoff levels, for the reasons discussed with respect to proposed §26.169(c). The proposed rule would add a requirement to report initial and confirmatory test results for additional drugs (if the FFD program tests for additional drugs), as well as a requirement to report the number of specimens with confirmed positive 6-acetylmorphine (6-AM) test results. (The proposed rule would include testing for 6-AM, because the presence of 6-AM in a

specimen uniquely identifies heroin use.) In addition, the proposed rule would add requirements to report the results of validity testing. These proposed changes would be made to conform the laboratory's annual summary report to other changes in the proposed rule, as discussed with respect to proposed §§26.217(b)(2), §26.185(f)(1), and 26.31(d)(3)(i).

Subpart H – Determining Fitness-for-Duty Policy Violations and Determining Fitness

Section 26.181 Purpose

Proposed §26.181 [Purpose] would describe the purpose of Subpart H, which is to establish requirements for MRO reviews of non-negative confirmatory drug test results and for making determinations of fitness. This proposed section would provide an overview of the contents of the proposed subpart, consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Section 26.183 Medical review officer

Proposed §26.183 [Medical review officer] would be added to present requirements related to the qualifications, relationships, staff, and responsibilities of the MRO to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, by grouping these requirements together in a single section.

Proposed §26.183(a) [Qualifications] would combine and amend the requirements in current §26.3 [Definitions] and Section 1.2 of Appendix A to Part 26, as well as portions of current Section 2.9(b) in Appendix A to Part 26. The proposed rule would reorganize the current requirements to eliminate redundancies and group together in one paragraph the

related provisions in the current rule to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

The proposed paragraph would amend portions of the current requirements related to MRO qualifications. The proposed paragraph would continue to provide that the MRO must be a licensed physician, but would clarify that the MRO may hold either a Doctor of Medicine or Doctor of Osteopathy degree for consistency with the related regulations of other Federal agencies. The proposed rule would add a requirement that the MRO must be knowledgeable of Part 26 and the FFD policies and procedures of the licensees and other entities for whom the MRO provides services. The proposed requirements of this part, and the policies and procedures of various Part 26 FFD programs, may differ from those of other workplace drug and alcohol testing programs for which an MRO provides services. This proposed provision would ensure that an MRO is able to perform his or her function appropriately under this part. In addition, the proposed rule would add a requirement that, within 2 years following the date on which this rule is published in the Federal Register, the MRO must pass an MRO certification examination. The proposed requirement would increase consistency in the performance of the MRO function among FFD programs, given that licensees and other entities would be permitted to accept test results and the results of determinations of fitness conducted by other licensees and entities who are subject to the rule. The 2-year implementation date would provide MROs who are not currently certified with an opportunity to pass the required examination. With the exception of the first sentence of this proposed paragraph, which specifically relates to the MRO function under Part 26, these MRO qualification requirements would be consistent with those of other Federal agencies.

Proposed §26.183(b) [Relationships] would establish requirements related to the relationships that would be permitted or prohibited between the MRO, the licensee or other

entity, and HHS-certified laboratories. The first sentence of the proposed paragraph would retain the portion of the first sentence of current Section 2.9(b) in Appendix A to Part 26 that permits the MRO to be an employee of a licensee or other entity, or a contractor. The remaining sentences of the proposed paragraph would be added to prohibit the MRO from being an employee or agent of, or have any financial interest in, a laboratory or a contracted operator of a licensee testing facility for whom the MRO reviews drug testing results for the licensee or other entity. The proposed prohibition would be added based upon the experiences of other Federal agencies and would be consistent with the related provision in the HHS Guidelines.

Proposed §26.183(c) [Responsibilities] would reorganize and update the requirements in current §26.3 [Definitions] as well as Sections 1.2, 2.4(j), 2.7(d), and 2.9(a) and (b) in Appendix A to Part 26 as they relate to the responsibilities of the MRO in Part 26 programs. The proposed rule would reorganize the current provisions and combine them in one paragraph. In addition, the terminology used in the proposed paragraph would be revised to be consistent with that used throughout the proposed rule (e.g., “non-negative”). The proposed changes would meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.183(c) would retain the requirement in current Section 2.9(a) in Appendix A to Part 26 for the MRO to review positive confirmatory drug test results and add a requirement for the MRO to review non-negative results from validity testing, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The proposed paragraph would also require the MRO to (1) identify evidence of subversion of the testing process; (2) identify issues or problems associated with the collection and testing of specimens; and (3) work with FFD program

management to assure the overall effectiveness of the FFD program. The proposed rule would add these responsibilities to clarify that the MRO carries programmatic responsibilities within a licensee's or other entity's FFD program, in addition to responsibility for reviewing drug and specimen validity test results. These proposed additional responsibilities would strengthen the effectiveness of FFD programs by ensuring that the MRO's expertise is brought to bear in the management of FFD programs. The proposed paragraph would also increase the consistency of the MROs' responsibilities under Part 26 with the responsibilities of MROs in the drug and alcohol testing programs of other Federal agencies. Therefore, the proposed changes would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, and Goal 3, which is to improve the effectiveness and efficiency of FFD programs.

Proposed §26.183(c)(1) would retain and update the requirements contained in the current definitions of the term, "Medical Review Officer," in §26.3 and Sections 1.2 and 2.9(b) in Appendix A to Part 26. The proposed rule would continue to require the MRO to examine alternate medical explanations for any non-negative test result, which would include non-negative results of confirmatory validity testing as well as positive confirmatory drug test results. The proposed paragraph would also retain the current requirement for the MRO to interview the donor and review the donor's medical history and any other relevant biomedical factors as well as all medical records that the donor may make available to the MRO. In addition to the responsible use of legally prescribed medication, the proposed rule would require the MRO to consider a documented condition or disease state and the demonstrated physiology of the donor in determining whether a non-negative test result is an FFD policy violation. The proposed rule would require the MRO to consider the latter factors because they may cause some non-negative validity test results. The proposed changes would be necessary for

consistency with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i), as well as to increase the consistency of Part 26 with advances in other relevant Federal rules and guidelines, which is Goal 1 of this rulemaking.

Proposed §26.183(c)(2) would retain the meaning of the last sentence of current Section 2.9(b) in Appendix A to Part 26 with minor editorial revisions for consistency with the terminology used throughout the proposed rule. For example, the proposed rule would replace the term," split samples," in the current sentence with the term, "split specimens." The proposed changes would be made for increased clarity in the language of the rule.

Proposed §26.183(d) [MRO staff] would be added to establish requirements related to individuals who provide routine administrative support functions to MROs, whether the individuals are employees of the licensee or other entity, employees of the MRO, or employees of an organization with whom the licensee or other entity contracts for MRO services. The proposed rule would add requirements related to MRO staff because these individuals (1) have access to drug test results that are forwarded to an MRO from the HHS-certified laboratory; (2) perform some administrative functions for MROs that permit them to view donors' private medical information; and (3) often have contact with donors. The NRC is not aware of any instances in which individuals who serve as MRO staff have compromised the confidentiality of donors' test results, medical information, or otherwise acted improperly in Part 26 programs. However, the proposed rule would adopt requirements related to the MRO staff function from the regulations of other Federal agencies who similarly permit MRO staff to provide administrative support to MROs to ensure that donors' medical information is handled with the highest concern for individual privacy. The proposed requirement would also ensure that information related to non-negative test results is not released to licensee or other entity

management personnel until the MRO has determined that a donor has violated the FFD policy. These proposed changes would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, and Goal 7, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Proposed §26.183(d)(1) [Direction of MRO staff activities] would be added to require an MRO to be directly responsible for the administrative, technical, and professional activities of individuals who perform MRO staff duties. The NRC does not intend, through use of this language, to mandate that MROs must share the same physical space with all their staff members at all times. Direction of staff activities need not occur face-to-face on an all-day, every-day basis. Direction may also take place through using a variety of electronic communications. However, the proposed rule would require that the MRO's direction of staff must be meaningful. Meaningful direction would involve (1) personal oversight of staff members' work; (2) personal involvement in their performance evaluation, hiring, and firing; (3) line authority over the staff for decisions, direction and control; and (4) regular contact and oversight concerning drug testing program matters. The proposed rule would also require that the MRO's direction and control of the staff members cannot be superseded by or delegated to anyone else with respect to the review of negative tests and other functions that staff members perform for the MRO. In addition, the proposed rule would require that MROs must personally review a confirmed positive drug test result that is received from the HHS-certified laboratory, as well an adulterated or substituted result, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.183(d)(1)(i) would require that MRO staff duties must be independent from any other activity or interest of the licensee or other entity. The proposed rule would add this requirement because, by contrast to other Federal agencies' regulations, Part 26 permits employees of licensees and other entities to perform MRO staff activities for MROs who work off site and are not physically present to supervise the staff. These circumstances may provide greater opportunities for inadvertent compromise of the independence of the MRO function than situations in which the MRO and his or her staff are physically co-located, such as the inadvertent release of non-negative test results before the MRO has reviewed the results with the donor. Therefore, the NRC believes that the proposed requirement is necessary to protect the integrity of the MRO function and donors' privacy.

Proposed §26.183(d)(ii) would be added to further specify the MRO's responsibilities for directing MRO staff. These responsibilities would include, but would not be limited to, ensuring that the procedures that must be followed by MRO staff meet the regulations of this part and HHS' and professional standards of practice, and that personal information about the donor is maintained confidential with the highest regard for individual privacy. The proposed requirements would meet Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Proposed §26.183(d)(1)(iii) would also be added to prohibit the MRO from delegating his or her responsibilities for directing MRO staff activities to any individual or entity, other than another MRO. Although the NRC is unaware of any instances in which the MRO function has been compromised by MRO staff in Part 26 programs, the experience of other Federal agencies has indicated that clear limits on who may direct MRO staff activities are advisable to maintain the independence and integrity of the MRO function. Therefore, proposed §26.183(d)(1)(iii) would establish these clear limits.

Proposed §26.183(d)(2) [MRO staff responsibilities] would be added to specify the job duties that MRO staff may and may not perform. The proposed provisions would also be based on the experience of other Federal agencies, which has indicated that clear limits on MRO staff job duties are necessary to protect donor confidentiality and the integrity of the MRO process. Proposed §26.183(d)(2)(i) would permit MRO staff to receive from the HHS-certified laboratory, review, and report negative test results to the licensee's or other entity's designated reviewing official, under the MRO's direction. Proposed §26.183(c)(2)(ii) would permit MRO staff to review the custody-and-control forms for specimens that the laboratory reports as non-negative and correct errors, but would require the MRO to review and approve the corrections. Proposed §26.183(d)(2)(iii) would prohibit staff from conducting interviews with donors to discuss non-negative test results and requesting or reviewing medical information from donors related to any non-negative test results. Proposed §26.183(c)(2)(iv) would prohibit MRO staff from reporting or discussing non-negative test results received from the HHS-certified laboratory with any individuals other than the MRO and other MRO staff. The proposed provisions would be necessary to protect donor confidentiality and the integrity of the MRO review process while permitting licensees and other entities to realize the cost efficiencies associated with the MRO delegating some tasks to staff.

Section 26.185 Determining a fitness-for-duty policy violation

Proposed §26.185 [Determining a fitness-for-duty policy violation] would amend requirements related to the MRO's determination that a non-negative test result constitutes an FFD policy violation, as follows:

Proposed §26.185(a) [MRO review required] would amend portions of current Section 2.9(a) in Appendix A to Part 26, which establishes requirements for the MRO's review

of test results from the HHS-certified laboratory. The term, “non-negative test result,” would be used in the proposed paragraph to indicate that the MRO’s review would encompass validity test results, as well as drug test results, consistent with the addition of validity testing requirements in the proposed rule. The proposed paragraph would also expand the MRO’s responsibilities to include assisting the licensee or other entity in determining whether a donor has attempted to subvert the testing process. These responsibilities may include, but would not be limited to, reviewing non-negative validity test results and authorizing the testing at an HHS-certified laboratory of any suspicious substance discovered in a donor’s pockets that could be used to adulterate or substitute a urine specimen. The proposed change would be consistent with the NRC’s increased concern with potential subversion of the testing process, as discussed with respect to proposed §26.31(d)(3)(i). The proposed rule would also delete the current reference to “nuclear power plant worker” and replace it with “individual,” because persons other than nuclear power plant workers would be subject to the proposed requirement. In addition, the proposed rule would eliminate the current requirement for the MRO to review blood test results from the HHS-certified laboratory because the proposed rule would no longer permit donors to request testing of a blood specimen for alcohol, as discussed with respect to proposed §26.83(a). However, the proposed paragraph would retain the current requirement that the MRO must complete the review of any non-negative test results before transmitting results to a licensee’s or other entity’s designated representative.

Proposed §26.185(b) [Reporting of initial test results prohibited] would retain the intent of the requirement in the last sentence of current Section 2.9(a) in Appendix A to Part 26. Specifically, the proposed rule would continue to prohibit the MRO from communicating to licensees and other entities any non-negative initial test results reported by the HHS-certified laboratory before confirmatory testing has been completed and the MRO has conducted his or

her review. However, the proposed rule would extend this prohibition to MRO staff, consistent with the addition of requirements related to MRO staff in proposed §26.183(d), as discussed with respect to that paragraph.

Proposed §26.185(c) [Discussion with the donor] would amend current Section 2.9(c) in Appendix A to Part 26. The proposed rule would continue to require the MRO to discuss a positive confirmatory drug test result with the donor before determining that the FFD policy had been violated. The proposed rule would add a requirement for the MRO to discuss non-negative confirmatory validity test results with the donor as part of the review process, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i). The proposed rule would add a reference to "other occurrence" to address circumstances in which the donor may have engaged in a subversion attempt that would be detected through other means, including, but not limited to, the specimen collection process in proposed Subpart E [Collecting Specimens for Testing]. The proposed rule would eliminate the current requirement for the MRO to contact the EAP. Under the proposed rule, referral to the EAP would be at the licensee's or other entity's discretion, as documented in FFD procedures. The current requirement would be eliminated because most licensees terminate the employment of individuals who have a confirmed non-negative drug test result, and it would be inappropriate to require licensees and other entities to provide EAP services to persons they will no longer employ. If a licensee or other entity plans to consider granting authorization to the individual after his or her authorization has been terminated unfavorably for the FFD policy violation, the proposed rule would require the licensee or other entity to meet the applicable requirements of proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information]. The changes in

the proposed paragraph would be made for consistency with other proposed changes to the regulation.

Proposed §26.185(d) [Donor unavailability] would be added to clarify the circumstances in which the MRO may confirm a non-negative test result or other occurrence as an FFD policy violation without having first discussed the test result or occurrence with the donor. These circumstances would include (1) the donor expressly declining the opportunity to discuss the possible FFD policy violation with the MRO in proposed §26.185(d)(1); (2) the donor failing to contact the MRO within one business day after being contacted by the licensee or other entity or an MRO staff member in proposed §26.185(d)(2); and (3) the MRO being unable to contact the donor after making a reasonable effort to do so in proposed §26.185(d)(2). The proposed paragraphs would provide more detailed guidance than the first sentence of current Section 2.9(c) in Appendix A to Part 26, in response to the many questions that have arisen regarding implementation of the requirement for MROs to discuss test results with the donor. The proposed revisions would also respond to stakeholders requests during the public meetings discussed in Section V. In questions to the NRC staff and during the public meetings, licensees have pointed out that the current rule makes no provision for these circumstances, which do occasionally arise. Therefore, the proposed paragraphs would address these circumstances.

For the same reasons, proposed §26.185(e) [Additional opportunity for discussion] would specify procedures for addressing a circumstance in which the donor was unable to contact the MRO to discuss a non-negative test result or other occurrence. The proposed paragraph would permit the donor to present information to the MRO documenting the circumstances that unavoidably prevented the donor from being contacted by or from contacting the MRO, and would permit the MRO to reopen the procedure for determining

whether the donor had violated the FFD policy. The proposed paragraph would also permit the MRO to modify the initial determination based on the information that the donor provides.

The requirements in proposed §26.185(d) and (e) would incorporate the related requirements in 49 CFR Part 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs" (65 FR 41944; August 9, 2001). Therefore, in addition to responding to implementation questions from licensees and stakeholder requests, the proposed provisions would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.185(f)–(i) would be added to establish requirements for the MRO's review of validity test results. These proposed paragraphs would be added for consistency with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i).

Proposed §26.185(f) [Review of invalid specimens] would clarify the MRO's responsibilities in the event that the HHS-certified laboratory reports that a specimen is invalid. The proposed paragraph would be consistent with related provisions in the HHS Guidelines, and would be necessary because MRO actions in response to an invalid specimen are not specified in the current rule. Proposed §26.185(f) would provide the MRO with several alternative courses of action if a specimen is declared to be invalid by the laboratory, as follows:

Proposed §26.185(f)(1) would require the MRO to consult with the HHS-certified laboratory to determine whether additional testing by another HHS-certified laboratory may be useful for completing testing of the specimen. Another laboratory may use different testing methods that could provide more definitive test results regarding the invalid specimen, such as the ability to identify a new adulterant or obtain valid drug test results despite the presence of an interfering substance in the specimen. If the MRO and laboratory agree that additional

testing would be useful, the MRO would direct the laboratory to forward an aliquot of the specimen to a second HHS-certified laboratory for further testing.

Proposed §26.185(f)(2) would require the MRO to contact the donor to determine whether there is an acceptable medical explanation for the invalid result, if the MRO and HHS-certified laboratory agree that testing at a second laboratory would not be useful. If the MRO determines that there is an acceptable medical explanation for the invalid result, the MRO would report to the licensee or other entity that no FFD policy violation had occurred, but that a negative test result had not been obtained. Because the specimen did not yield negative test results, the licensee or other entity could not use the invalid test result in the decision to grant or deny authorization. However, the proposed paragraph would also require the MRO to assess whether the medical condition would similarly affect a second specimen collection. If the MRO determines that the medical condition is temporary and would not affect a second specimen, he or she would direct the licensee or other entity to collect another specimen from the donor and the licensee or other entity would then rely upon the results of the second test to make an authorization decision. The proposed rule would not require the second specimen to be collected under direct observation in this situation, because there would be no reason to believe that the individual may have attempted to subvert the testing process. If the MRO determines that the medical condition would likely affect the validity of further urine specimens, the proposed paragraph would permit the MRO to authorize an alternative method for drug testing. At this time, the NRC declines to specify the alternative methods that the MRO may authorize, which may include, but would not be limited to, testing of alternate specimens, such as hair, oral fluids, or sweat. The NRC would leave the selection of an alternative method to the professional judgement of the MRO. The proposed rule also would prohibit licensees and other

entities from taking management actions or imposing sanctions on the basis of an invalid test result from a medical condition, because no FFD violation would have occurred.

Proposed §26.185(f)(3) would require the MRO to direct the licensee or other entity to collect another specimen under direct observation, if testing by another laboratory would not be useful in obtaining a valid result and the donor did not provide an acceptable medical explanation for the invalid specimen. The invasion of privacy associated with a directly observed collection would be warranted in this situation because the invalid specimen may be the result of a subversion attempt. The proposed rule would require the licensee or other entity to rely upon the test results from the directly observed collection in authorization decision-making because the result from the invalid specimen would be neither negative or non-negative, and so could not meet the requirements for granting authorization to an individual in proposed Subpart C [Granting and Maintaining Authorization] or serve as the basis for imposing the sanctions specified in proposed Subpart D [Management Actions and Sanctions].

Proposed §26.185(g) [Review of dilute specimens] would be added to establish requirements for the MRO's review of positive confirmatory drug test results from dilute specimens. The proposed paragraph would be added because reviewing test results from a dilute specimen is complex and MRO actions in response to a dilute specimen are not addressed in the current rule.

Proposed §26.185(g)(1) would require the MRO to confirm a drug-positive FFD violation for a dilute specimen in which drugs or drug metabolites are detected, if the MRO determines that there is no legitimate medical explanation for the presence of the drugs or metabolites in the specimen. There are many legitimate reasons for submitting a dilute specimen, which is the basis for omitting the submission of a dilute specimen as one type of subversion attempt for which a permanent denial of authorization would be required in proposed §26.75(b). Although

neither the submission of a dilute specimen nor the presence of drugs or drug metabolites in a dilute specimen establishes that the donor has attempted to subvert the testing process without additional evidence of subversion, the presence of drugs or metabolites in a dilute specimen without a legitimate medical explanation is a sufficient basis for the MRO to confirm that the donor has violated the FFD policy.

Proposed §26.185(g)(2) would permit the MRO to require the HHS-certified laboratory to test a dilute specimen for drugs and drug metabolites at the LOD of the confirmatory assay used, if the MRO has reason to believe that the donor may have attempted to subvert the testing process. The proposed rule would authorize the MRO to request testing at the LOD for any drugs or drug metabolites for which testing would be permitted in this part. The MRO would be permitted to request testing at the LOD in these circumstances because the immunoassay tests used for initial drug testing may not be sufficiently sensitive to detect very low concentrations of drugs or metabolites in a dilute specimen. However, confirmatory testing at the LOD may detect very low concentrations of drugs or metabolites in a dilute specimen and, therefore, would ensure that an attempt to hide drug abuse through specimen dilution is unsuccessful.

Proposed §26.185(g)(2)(i)–(g)(2)(iii) would define the circumstances that constitute a reason to believe that a donor may have attempted to subvert the testing process and provide a sufficient basis for the MRO to require the additional testing permitted in proposed §26.185(g)(2). These circumstances would be the same as those specified in proposed §26.115(a)(1)–(a)(3), as discussed with respect to those provisions.

Proposed §26.185(g)(3) would clarify that the MRO may also require the additional testing of a dilute specimen that would be permitted in proposed §26.185(g)(2), if the specimen was collected under direct observation, or if such testing is required by the SAE as a result of a

determination of fitness conducted under proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information]. The proposed paragraph would add these permissions for consistency with the related provisions in the proposed rule.

Proposed §26.185(g)(4) would require the MRO to determine whether there is clinical evidence of the illegal use of opiates, if opiates other than 6-AM at any concentration are detected in a dilute specimen, before the MRO verifies that the donor has violated the FFD policy. The proposed rule would not require an evaluation for clinical evidence of illegal use of opiates for 6-AM, because it's presence in a specimen is proof of heroin use. However, the proposed paragraph would not establish cutoff levels below and above which an evaluation for clinical evidence of illegal opiate use is not required (in contrast to those contained in proposed paragraph (j) of this section), because the concentration of opiates in a dilute specimen would not bear any known relationship to the concentration of opiates in vivo (i.e., in the donor's body). For similar reasons, the proposed rule would also require an evaluation for clinical evidence of abuse before the MRO determines that the donor has violated the FFD policy when drugs or drug metabolites are detected in a dilute specimen, indicating that the donor has used prescription or over-the-counter medications.

Proposed §26.185(h) [Review of substituted specimens] would be added to establish requirements for the MRO review of substituted test results. The proposed provisions would be added because MRO actions in determining an FFD policy violation for a substituted specimen are not addressed in the current rule. The proposed provisions would be consistent with the related provisions in the HHS Guidelines.

Proposed §26.185(h)(1) would require the MRO to contact the donor to determine whether there is a legitimate medical reason for the substituted result. The proposed paragraph would require the MRO to give the donor the opportunity to provide legitimate

medical evidence, within 5 business days of being contacted by the MRO, that the individual's normal physiology produced the substituted result and would establish requirements for the medical evidence that would be necessary. The proposed rule would also provide examples of donor claims that the MRO may not consider to be legitimate medical explanations, including, but not limited to, race, gender, body weight, and dietary factors.

Proposed §26.185(h)(2) would direct the MRO to report to the licensee or other entity that the specimen was substituted, if the MRO determines that there is no acceptable medical explanation for the substituted test result.

Proposed §26.185(h)(3) would direct the MRO to report to the licensee or other entity that no FFD policy violation has occurred, if the MRO determines that the donor has provided an acceptable medical explanation for the substituted test result.

Proposed §26.185(i) [Review of adulterated specimens] would establish requirements for the MRO's review of adulterated test results. The proposed provisions would be added because MRO actions in determining an FFD policy violation for an adulterated specimen are not addressed in the current rule. Proposed §26.185(i)(1) would require the MRO to contact the donor and offer him or her the opportunity to provide an acceptable medical explanation for the adulterated result. The proposed rule would also specify the procedures that the donor must follow in providing the medical explanation. If the donor does not provide an acceptable medical explanation for the adulterated result, proposed §26.185(i)(2) would require the MRO to report to the licensee or other entity that the specimen is adulterated. If the donor provides an acceptable medical explanation, proposed §26.185(j)(3) would require the MRO to report that no FFD policy violation had occurred. These proposed requirements would be consistent with the related provisions in the HHS Guidelines.

Proposed §26.185(j) [Review for opiates, prescription and over-the-counter medications] would amend current Section 2.9(d) in Appendix A to Part 26 to address circumstances that have arisen since Part 26 was first published and about which licensees have sought guidance from the NRC. The proposed paragraph would amend the current requirements in Section 2.9(d) in Appendix A to Part 26 and add others, as follows:

Proposed §26.185(j)(1) would incorporate updated requirements from the HHS Guidelines related to the MRO's review of a positive drug test result for opiates. The proposed rule would revise, but retain the meaning of the requirement for the MRO to determine that there is clinical evidence of illegal use of opiates, which appears in current Section 2.9(d) in Appendix A to Part 26. Because some licensees and other entities rely on MROs who work off site and are not available to conduct the required assessment, the proposed rule would permit the MRO to designate another licensed physician who has knowledge of the clinical signs of drug abuse to conduct the evaluation. The proposed change would continue to ensure that the clinical assessment is performed by a qualified physician while reducing unnecessary burden by permitting FFD programs to continue to rely on off-site MROs. Therefore, the proposed change would meet Goal 5 of this rulemaking, which is to improve Part 26 by eliminating or modifying unnecessary requirements.

The proposed rule would make other changes to current Section 2.9(d) in Appendix A to Part 26. The proposed paragraph would eliminate the examples of clinical signs of opiate abuse in current Section 2.9(d), because these signs are addressed as part of the training that MROs would obtain in order to pass the comprehensive certification examination required in proposed §26.183(a) [Qualifications]. The proposed rule would retain the provision in current Section 2.9(d) that permits the MRO to omit the evaluation for clinical evidence of abuse if the laboratory identifies 6-AM in the specimen. However, the proposed rule would add permission

for the MRO to omit the evaluation if the morphine or codeine concentration in the specimen is equal to or greater than 15,000 ng/mL without a legitimate medical explanation for the presence of opiates at or above this concentration. The proposed change would be made because, in the experience of other Federal programs, such concentrations without a legitimate medical explanation can only indicate substance abuse. In addition, the proposed rule would prohibit the MRO from considering consumption of food products as a legitimate medical explanation for the specimen having morphine or codeine concentrations at or above 15,000 ng/mL, given that food consumption could not result in a concentration at this level.

Proposed §26.185(j)(2) would retain the last sentence of current Section 2.9(d) in Appendix A to Part 26, which requires the MRO to determine whether there is clinical evidence, in addition to the positive drug test result, of abuse of these substances or their derivatives.

Proposed §26.185(j)(3) would be added to provide greater consistency in MRO determinations related to a donor's use of another person's prescription medication. The NRC is aware that MROs in different FFD programs have varied in the determination they make as to whether the use of another person's prescription medication is an FFD policy violation. The proposed paragraph would clarify the NRC's intent with respect to these circumstances. In the proposed rule, if a donor claims, and the MRO confirms, that a non-negative drug test result is due to the unauthorized use of another person's prescription medication, the proposed rule would require the MRO to evaluate or ensure that the donor is evaluated for clinical evidence of abuse. If no clinical evidence of abuse is identified, the MRO would report to the licensee or other entity that a violation of the FFD policy regarding misuse of a prescription medication had occurred. If clinical evidence of abuse is identified, the MRO would confirm that the test results are positive for the drug or metabolites detected.

Proposed §26.185(j)(4) would be added to assure greater consistency in MRO determinations related to a donor's use of a prescription or over-the-counter medication that the donor obtained legally in a foreign country. Again, the NRC is aware that MROs in different FFD programs have varied in the determination they make as to whether the use of medications legally obtained in a foreign county is an FFD policy violation. The proposed paragraph would clarify the NRC's intent with respect to these circumstances. At the licensee's or other entity's discretion and in accordance with the FFD policy and procedures, the proposed rule would permit the MRO to confirm a test result as negative if there is a legitimate medical use for the medication that the donor obtained legally in a foreign country and the donor has used it properly for its intended medical purpose. The proposed rule would prohibit the MRO from confirming a test result as negative if the drug used has no legitimate medical purpose, including, but not limited to phencyclidine and heroin.

Proposed §26.185(j)(5) would be added to prohibit the MRO from considering the consumption of food products, supplements, and other preparations that are available over-the-counter as a legitimate medical explanation for the specimen having drugs or drug metabolites above the cutoff levels specified in proposed §26.163, including, but not limited to hemp products and coca leaf tea. In so doing, the proposed rule would provide guidance concerning a potential subversion technique that has become an issue for several licensees (i.e., claims of ingestion of hemp food products as the basis for a positive marijuana test). Ingestion of food products containing hemp seeds or extracts has produced marijuana positive test results, even though the seller claimed that the seeds or extracts were sterilized to remove the THC metabolite. The NRC endorses the Federal policy in this matter that was published by the Department of Transportation, with the concurrence of the Departments of Justice and Health and Human Services and the Office of National Drug Control Policy. MROs must never accept

an assertion of consumption of a hemp food product as a basis for confirming that a marijuana test is negative. Consuming a hemp food product is not a legitimate medical explanation for a prohibited substance or metabolite in an individual's specimen. When a specimen is positive for THC, the only legitimate medical explanation for its presence is a prescription for marinol. Under proposed §26.29(a)(6) and (a)(7), individuals who are subject to Part 26 would receive training in order to be able to avoid ingesting substances that could result in positive drug test results, such as over-the-counter medications, food products, supplements, and other preparations.

Proposed §26.185(j)(6) would be added to prohibit the MRO from accepting the use of any drugs that are listed in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812] as a legitimate medical explanation for a positive confirmatory drug test result, even if the drug may be legally prescribed and used under State law. Drugs that are listed in Schedule I of section 202 of the Controlled Substances Act have the following characteristics: (1) the drug or other substance has a high potential for abuse; (2) the drug or other substance has no currently accepted medical use in treatment in the United States; and (3) there is a lack of accepted safety for use of the drug or other substance under medical supervision. The proposed prohibition would primarily be intended to address the medical use of marijuana, which some States permit, as well as the use of certain hallucinogenic drugs. Although some have argued that the use of such drugs under State laws may not adversely reflect on an individual’s trustworthiness and reliability, the proposed requirement would be necessary to ensure that individuals who are subject to this part can be trusted and relied upon to comply with Part 26 requirements and are not impaired from using these drugs when performing duties that require them to be subject to this part.

Proposed §26.185(k) [Results consistent with legitimate drug use] would amend current Section 2.9(f) in Appendix A to Part 26. The current paragraph instructs the MRO to report to the licensee that a drug test result is negative if, after review, the MRO determines that there is a legitimate medical explanation for the positive test result and that use of the substance identified through testing in the manner and at the dosage prescribed does not reflect a lack of reliability and is unlikely to create on-the-job impairment. However, the current provision does not provide instructions for MRO action in the case of an individual whose drug use is legitimate but may cause impairment on duty. Therefore, if the MRO determines that a risk exists, the proposed rule would require that a determination of fitness must be performed. Because the MRO determined that the drug test result was negative, the licensee or other entity would not impose sanctions on the individual. However, the results of the determination of fitness may indicate a need to establish controls and conditions on the individual's performance of certain job duties, in order to ensure that any impairment from the drug use does not result in adverse impacts on public health and safety or the common defense and security. The proposed provision would meet Goal 3 of this rulemaking, which is to improve the effectiveness of FFD programs, by providing greater assurance that individuals who are subject to the rule are fit to safely and competently perform their duties.

Proposed §26.185(l) [Retesting authorized] would amend current Section 2.9(e) in Appendix A to Part 26, which permits the MRO to authorize retesting of an aliquot of a specimen if there is any question about the accuracy or validity of a drug test result. The proposed rule would retain the provisions in current Section 2.9(e) that permit a donor to request a retest of an aliquot of a single specimen or a split specimen, if the FFD program follows split specimen procedures. However, the proposed rule would update the current requirement for consistency with the terminology used throughout the proposed rule (e.g.,

“Bottle B” to refer to a split specimen), as discussed with respect to proposed §26.5 [Definitions]. The proposed rule would also add a requirement that the retesting must be conducted at a second HHS-certified laboratory that did not conduct the original tests. The proposed requirement that retesting must be performed at a second HHS-certified laboratory would ensure the independence of the second testing and provide additional protection of donors’ due process rights under the proposed rule. In addition, the proposed requirement would increase the consistency of Part 26 with related provisions in the HHS Guidelines. The proposed rule would also require the donor to request the retest in writing, in order to ensure donors’ control over the specimen and rights to privacy, as discussed with respect to §26.135(b).

Proposed paragraph §26.185(m) [Results scientifically insufficient] would amend current Section 2.9(g) in Appendix A to Part 26, which permits the MRO to determine that a positive drug test result is scientifically insufficient and declare it negative. The proposed paragraph would change some of the terminology used in the current paragraph (e.g., “samples” would be changed to “specimens”) for consistency with the terminology used throughout the proposed rule, as discussed with respect to proposed §26.5 [Definitions]. The proposed rule would also make other changes to this paragraph, as follows:

The proposed paragraph would amend the first sentence of the current requirement, which permits the MRO to report to the licensee or other entity that a test result is negative if he or she determines that it is scientifically insufficient for further action. The proposed rule would instruct the MRO to report that the test result is “not an FFD policy violation” in these circumstances, rather than a negative test result. The proposed change would be made for consistency with other changes in the proposed rule related to invalid test results, as discussed with respect to proposed §26.185(f). That is, a test result that the MRO determines to be

scientifically insufficient for further action (as well as an invalid test result) could not be a basis for a licensee or other entity to grant or deny authorization or impose sanctions because it would be neither a negative nor non-negative test result. Therefore, the proposed change would meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

The proposed rule would also add a statement to the current paragraph to indicate that the MRO is neither expected nor required to request retesting of the specimen unless, in the sole opinion of the MRO, such retesting is warranted. The proposed rule would add this statement because, in the experience of other Federal agencies, some MROs have been pressured by the organization to whom they provide services to request retesting of specimens that the MRO has confirmed to be non-negative. Although the NRC is not aware of any such instances in Part 26 programs, the proposed rule would clarify that the MRO, alone, is authorized to request retesting to further protect the independence of the MRO function.

In addition, the last sentence of current Section 2.9(g), which contains records retention requirements, would be moved to §26.215(b)(11) of proposed Subpart J [Recordkeeping and Reporting Requirements] and grouped with other records retention requirements in the proposed rule for organizational clarity.

Proposed §26.185(n) [Evaluating results from a second laboratory] would establish new requirements for the MRO's determination of an FFD policy violation based on a retest of a single specimen or a test of the specimen in Bottle B of a split specimen. The proposed paragraph would specify that the test result(s) from the second HHS-certified laboratory would supersede the confirmatory test results provided by the HHS-certified laboratory that performed the original testing of the specimen. The proposed rule would incorporate these requirements from the HHS Guidelines because the current rule does not address MRO actions in response to test results from a second laboratory. Therefore, the proposed paragraph would be

consistent with the related provisions in the HHS Guidelines and would meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Proposed §26.185(o) [Re-authorization after a first violation] would be added to address the MRO's review of drug test results following a first violation of the FFD policy based on a confirmed positive drug test result. The current rule does not require the MRO to evaluate whether drug test results in these instances indicate subsequent drug use after a first confirmed positive drug test result, and MROs from different FFD programs have implemented different policies. Specifically, the proposed paragraph would require the MRO to determine whether subsequent drug test results indicate further drug use since the first positive drug test result was obtained. For example, because marijuana metabolites are fat-soluble and may be released slowly over an extended period of time, a second positive test result for marijuana from a test that is performed within several weeks after a first confirmed positive test result for marijuana may not, in fact, indicate further marijuana use. Therefore, in this case, the proposed provision would prohibit the MRO from determining that a second FFD policy violation for marijuana had occurred, if the quantitative results from confirmatory testing of the second specimen are positive for marijuana metabolites, but at a concentration that would be inconsistent with additional marijuana use since the first non-negative test result was obtained. If the MRO concludes that the concentration of marijuana metabolites identified by confirmatory testing is inconsistent with further marijuana use since the first positive test result, the MRO would declare the test result as negative, even if the quantitative test result exceeds the 15 ng/mL confirmatory cutoff level specified in this part or a licensee's or other entity's more stringent cutoff level. The proposed provision would prevent individuals from being subject to a 5-year denial of authorization for a second confirmed positive drug test result under proposed

§26.57(e), when the donor has not engaged in further drug use, consistent with Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Proposed §26.185(p) [Time to complete MRO review] would amend current §26.24(e), which requires the MRO to complete his or her review of test results and notify management of the results of his or her review within 10 days after an initial presumptive positive screening test result. The proposed rule would replace the current phrase, “initial presumptive positive screening test result,” with the phrase, “initial non-negative test result,” for consistency with the terminology used throughout the proposed rule, as discussed with respect to proposed §26.5 [Definitions]. The proposed paragraph would also require the MRO to report his or her determination that a non-negative test result is an FFD policy violation in writing to the licensee or other entity and in a manner that ensures the confidentiality of the information. The proposed changes would be made for consistency with the related provisions in the HHS Guidelines.

Section 26.187 Substance abuse expert

A new §26.187 [Substance abuse expert] would be added to establish minimum requirements for a new position within FFD programs, the “substance abuse expert” (SAE), for the reasons discussed in Section IV. C.

Proposed §26.187(a) [Implementation] would be added to require SAEs to meet the requirements of this proposed section within 2 years of the date on which the final rule is published in the Federal Register. The 2-year period would be proposed in order to ensure that professionals who may currently be performing determinations of fitness, but who do not meet

these proposed requirements, have the time necessary to obtain the required credentials, knowledge, and qualification training.

Proposed §26.187(b) [Credentials] would be added to establish the credentials required for an individual to serve as an SAE under this part. The proposed rule would require that the SAE must possess the extensive education, training, and supervised clinical experience that are prerequisites for obtaining the professional credentials listed in proposed §26.187(b)(1)–(b)(5). However, proposed §26.187(c)–(e) would require an SAE to possess additional knowledge and experience directly related to substance abuse disorders and the requirements of this part.

Proposed §26.187(c) [Basic knowledge] and (d) [Qualification training] would be added to establish the specific areas of expertise and training that would be required for an individual to serve as an SAE under this part. The proposed knowledge and training requirements in these two paragraphs would be necessary to ensure that SAEs possess the knowledge and clinical experience required to perform the SAE function effectively in a Part 26 program.

Proposed §26.187(c) would require SAEs to possess the following types of knowledge: (1) knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled-substance abuse disorders, in proposed §26.187(c)(1); (2) knowledge of the SAE function as it relates to individuals who perform the job duties that require an individual to be subject to this part, in proposed §26.187(c)(2); and (3) knowledge of this part and any changes to its requirements, in proposed §26.187(c)(3).

Proposed §26.187(d) would establish the topical areas in which an SAE must be trained. The proposed qualification training requirements would include training in the following areas: (1) the background, rationale, and scope of this part, in proposed §26.187(d)(1); (2) key drug and alcohol testing requirements of this part, in proposed §26.187(d)(2) and (d)(3), respectively;

(3) SAE qualifications and prohibitions, in proposed §26.187(d)(4); (4) the role of the SAE in making determinations of fitness, and developing treatment recommendations and followup testing plans, in proposed §26.187(d)(5); (5) procedures for consulting and communicating with licensee or other entity officials and the MRO, in proposed §26.187(d)(6); (6) reporting and recordkeeping requirements of this part as they related to the SAE function, in proposed §26.187(d)(7); and (7) appropriate methods for addressing issues that SAEs confront in carrying out their duties under this part, in proposed §26.187(d)(8).

Proposed §26.187(e) [Continuing education] would be added to ensure that SAEs maintain the knowledge and skills required to perform the SAE function under this part. The proposed paragraph would require SAEs to complete at least 12 continuing professional education hours relevant to performing the SAE function during each 3-year period following completion of initial qualification training. Proposed §26.187(e)(1) would describe the topics that must be covered in the continuing education training, to include, but not limited to, new drug and alcohol testing technologies, and any rule interpretations or new guidance, rule changes, or other developments in SAE practice under this part, since the SAE completed the qualification training requirements in proposed §26.187(d). Proposed §26.187(e)(2) would require documented assessment of the SAE's understanding of the material presented in the continuing education activities in order to ensure that the SAE learned the material. These proposed continuing educations requirements would necessary to ensure that SAEs maintain updated knowledge and skills to continue performing the SAE function effectively under this part.

Proposed §26.187(f) [Documentation] would be added to specify the records that the SAE must maintain in order to demonstrate that he or she meets the proposed requirements of this section. The SAE would be required to provide the documentation, as requested, to NRC

representatives, and to licensees or other entities who would rely on the SAE's services. Licensees and other entities who intend to rely upon a determination of fitness that is made by an SAE under another FFD program would also be required to have access to this documentation. These proposed requirements would be necessary to ensure that licensees and other entities, and the NRC, have access to the documentation required to verify that the SAE's knowledge, training, and practice meet the requirements of this part.

Proposed §26.187(g) [Responsibilities and prohibitions] would be added to specify the responsibilities of SAEs within a licensee's or other entity's FFD program and their limitations.

Proposed §26.187(g)(1) would specify at least three circumstances in which the SAE would be responsible for making a determination of fitness under the proposed rule. In proposed §26.187(g)(1)(i), an SAE may be called upon to make a determination of fitness regarding an applicant for authorization when the self-disclosure, the suitable inquiry, or other sources of information identify potentially disqualifying FFD information about the applicant. In proposed §26.187(g)(1)(ii), an SAE may be called upon to make a determination of fitness when an individual has violated the substance abuse provisions of a licensee's or other entity's FFD policy, including, but not limited to a first confirmed positive drug test result. Related provisions in proposed §26.69 [Authorization with potentially disqualifying FFD information] would require the licensee or other entity to rely upon the results of the SAE's determination of fitness when making a decision to grant or maintain an individual's authorization and implement any recommendations from the SAE for treatment and followup testing. In proposed §26.187(g)(1)(iii), an SAE may be called upon to make a determination of fitness when there is a concern that an individual may be impaired as a result of the use of prescription or over-the-counter medications, or alcohol. Related provisions in proposed §26.77 [Management actions regarding possible impairment] would require the licensee or other entity to rely upon the results

of the SAE's determination of fitness when determining whether an individual may perform job duties that require the individual to be subject to this part. Therefore, the proposed paragraph would be added for consistency with other, related provisions in the proposed rule.

Proposed §26.187(g)(2) would be added to require the SAE to act as a referral source to assist an individual's entry into an appropriate treatment or education program and prohibit the SAE from engaging in any activities that could create the appearance of a conflict of interest. Proposed §26.187(g)(2)(i) would prohibit the SAE from referring an individual to any organization with whom the SAE has a financial relationship, including the SAE's private practice, to avoid creating the appearance of a conflict of interest. However, proposed §26.187(g)(2)(ii)(A)–(g)(2)(ii)(D) would specify circumstances in which the prohibition in proposed §26.187(g)(2)(i) would not apply. In general, the proposed rule would permit the SAE to refer an individual to an entity with whom the SAE has a financial relationship in situations where treatment and educational resources may be limited by cost considerations or geographical availability. These proposed provisions would be necessary to ensure that the SAE's determinations are not influenced by financial gain and that individuals who are subject to the rule and the public can have confidence in the integrity and independence of the SAE function in Part 26 programs.

Section 26.189 Determination of fitness

Proposed §26.189 [Determination of fitness] would be added to present together in one section and amend current requirements related to the determination that an individual is fit to safely and competently perform the job duties that require individuals to be subject to this part. The terms, "medical assurance" and "medical determination of fitness," used in various sections of the current rule [e.g., §26.27(a)(3), (b)(2) and (b)(4)] would be replaced with the term,

“determination of fitness,” as defined in this proposed section. This proposed change in terminology would be made because the rule would permit healthcare professionals other than licensed physicians to conduct determinations of fitness, as discussed with respect to proposed §26.187 [Substance abuse expert]. Therefore, the proposed change would meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.189(a) would be added. The first sentence of the proposed paragraph would define the term, “determination of fitness.” This term would refer to the process followed to determine whether there are indications that an individual may be in violation of the licensee’s or other entity’s FFD policy or is otherwise unable to safely and competently perform his or her duties.

In general, the proposed rule would require that professionals who perform determinations of fitness must be qualified and possess the requisite clinical experience, as verified by the licensee or other entity, to assess the specific fitness issues presented by an individual whose fitness may be questionable. The proposed approach to designating the healthcare professionals who may conduct a determination of fitness focuses on the appropriateness of the professional’s expertise for addressing the subject individual’s fitness issue, rather than on the professional’s organizational affiliation [see the discussion of proposed §26.69(b)(4)] or whether the individual is a licensed physician. Therefore, proposed §26.189(a)(1)–(a)(5) would provide examples of the healthcare professionals who would be qualified to address various fitness issues that may arise in a FFD program. When a decision must be made to determine whether an individual may be granted or maintain authorization and a substance abuse disorder is involved, only professionals who meet the requirements to serve as an SAE would be permitted to make determinations of fitness under proposed §26.189(a)(1). The proposed rule would permit other healthcare professionals to perform determinations of

fitness that involve assessing and diagnosing impairment from causes other than substance abuse, such as clinical psychologists in proposed §26.189(a)(2), psychiatrists in proposed §26.189(a)(3), physicians in proposed §26.189(a)(4), or an MRO in proposed §26.189(a)(5), consistent with their professional qualifications. The proposed rule would also permit other licensed and certified professionals who are not listed in the proposed paragraph, such as registered nurses or physicians' assistants who have the appropriate training and qualifications, to perform a determination of fitness regarding specific fitness issues that are within their areas of expertise. However, the critical tasks of assessing the presence of a substance abuse disorder, providing input to authorization decisions, and developing treatment plans would be reserved for healthcare professionals who have met the specific training, clinical experience, and knowledge requirements for an SAE under proposed §26.187 [Substance abuse expert] for the reasons discussed with respect to that proposed section.

The proposed rule would also prohibit healthcare professionals who may conduct a determination of fitness for a Part 26 program from addressing fitness issues that are outside of their specific areas of expertise, consistent with the ethical standards of healthcare professionals' disciplines as well as State laws. The proposed rule would add this prohibition to clarify that the ethical standards and State laws also apply to making determinations of fitness under Part 26 because a determination of fitness conducted by a professional who is not qualified to address the specific fitness issue would be of questionable validity. Therefore, the proposed prohibition would be necessary to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs, as well as Goal 7, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Proposed §26.189(b)(1)–(b)(4) would list and present together the circumstances in which a determination of fitness must be performed, as required in other sections of the

proposed rule. Although this proposed paragraph would be redundant with other sections of the proposed rule, these circumstances would be listed in the proposed paragraph to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, by grouping related requirements together in the order in which they would apply to licensees' and other entities' FFD processes.

Proposed §26.189(b)(1) would reiterate the requirement in current Section 2.9(f) in Appendix A to Part 26 and proposed §26.185(k) that a determination of fitness must be performed when there is a medical explanation for a non-negative test result, but a potential for impairment exists. For example, legitimate use of some psychotropic medications or medications for pain relief may cause impairment in some individuals and it may be necessary to limit the types of tasks the individual performs until the medication is no longer necessary, or the person adjusts to its effects.

Proposed §26.189(b)(2) would reiterate requirements in current §26.27(b)(1) and (b)(4) and proposed §26.69(b) [Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization] that a determination of fitness must be performed before an individual is granted authorization following an unfavorable termination or denial of authorization for a violation of a licensee's or other entity's FFD policy.

Proposed §26.189(b)(3) would reiterate the requirement in proposed §26.69(c) [Granting authorization with other potentially disqualifying FFD information] that a determination of fitness must be performed before an individual is granted authorization when potentially disqualifying FFD information is identified that has not been previously addressed and resolved under a Part 26 FFD program.

Proposed 26.189(b)(4) would address other circumstances in which a determination of fitness may be required. For example, a determination of fitness may be necessary if an FFD

concern has been raised regarding another individual, as required in proposed §26.27(c)(4), and if a licensee's or other entity's reviewing official requires one, in accordance with proposed §26.69(c)(3) and (d)(2).

Proposed §26.189(c) would be added to establish requirements for a determination of fitness that is conducted "for cause." Specifically, proposed §26.189(c) would require that a determination of fitness that is conducted for cause must be conducted through face-to-face interaction to ensure that the professional who is performing the determination has available all of the sensory information that may be required for the assessment, such as the smell of alcohol or the individual's physical appearance. The immediacy of the decision would limit the amount of information that could be gathered and made available to the professional by others. Conversely, the proposed paragraph would not require that determinations of fitness for other purposes be conducted face-to-face. These other purposes may include, but would not limited to, the determination of fitness that would be required when an applicant for authorization has self-disclosed potentially disqualifying FFD information. Determinations of fitness in these other circumstances would focus primarily on historical, rather than immediate, information. The professional would have access to information that could be gathered by others about the individual, and no time urgency would be involved in the evaluation. Therefore, the proposed paragraph would be added to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs, by requiring a face-to-face assessment in some circumstances where electronic means of communication could not provide the requisite information for the evaluation, and permitting other means of conducting the assessment when those means provide increased flexibility to licensees and other entities while continuing to achieve the goal of the evaluation.

Proposed §26.189(c)(1)–(c)(4) would be added to specify the required outcomes of a for-cause determination of fitness. The proposed rule would provide an increased level of detail in these requirements to increase consistency in implementing the for-cause determination of fitness process among FFD programs for the reasons discussed with respect to proposed §26.187 [Substance abuse expert].

Proposed §26.189(c)(1) would require that, if there is neither conclusive evidence of an FFD policy violation nor a significant basis for concern that the individual may be impaired while on duty, then the individual must be determined to be fit for duty and the licensee or other entity must permit the individual to perform the job duties that require the individual to be subject to this part.

Proposed §26.189(c)(2) would require that, if there is no conclusive evidence of an FFD policy violation, but there is a significant basis for concern that the individual may be impaired while on duty, then the individual must be determined to be unfit for duty. Such a determination would not constitute a violation of Part 26 or the licensee's or other entity's FFD policy; therefore, no sanctions would be applied. Examples of circumstances in which an individual may be determined to be unfit under the proposed paragraph could include a temporary illness, such as a severe migraine headache, or transitory but severe stress in a personal relationship. These circumstances may impact an individual's ability to work safely for a short period, but would have no implications for the individual's overall fitness to perform the job duties that require the individual to be subject to this part. In addition, the proposed rule would require the professional who conducts the determination of fitness to consult with the licensee's or other entity's management personnel to identify and implement any necessary limitations on the impaired individual's activities to ensure that the individual's condition would not affect

workplace or public health and safety. If appropriate, the individual may be referred to the EAP for assistance.

Proposed §26.189(d) would be added to prohibit licensees and other entities from seeking a second determination of fitness if a determination of fitness under Part 26 has already been performed by a qualified professional who is employed by or under contract to the licensee or other entity. The proposed paragraph would also require that the professional who made the initial determination must be responsible for modifications to the initial determination based on new or additional information. If the initial professional is no longer available, then the licensee or other entity would be required to assist in arranging for consultation between the new professional and the professional who is no longer employed by or under contract to the licensee or other entity. The proposed paragraph would be necessary to ensure consistency and continuity in the treatment of an individual who may be undergoing treatment, aftercare, and followup testing.

Subpart I – Managing Fatigue

Section 26.195 Applicability

A new §26.195 [Applicability] would be added to specify the licensees and other entities to whom the requirements in proposed Subpart I would apply. Proposed Subpart I would apply only to licensees who are authorized to operate a nuclear power reactor (under §50.57 of this chapter) and holders of a combined license after the Commission has made the finding under §52.103 of this chapter, as specified in proposed §26.3(a), and C/Vs who implement FFD programs or program elements upon which such licensees rely, as specified in proposed §26.3(d).

As discussed in Section IV. D, the proposed rule would require nuclear power plant licensees to implement the requirements in Subpart I for the following reasons:

(1) Fatigue and decreased alertness can substantively degrade an individual's ability to safely and competently perform his or her duties;

(2) Conditions that contribute to worker fatigue are prevalent in the U.S. nuclear power industry;

(3) With the exception of NRC orders limiting the work hours of security personnel, the NRC's current regulatory framework does not include consistent requirements to prevent worker fatigue from adversely impacting safe operations and enforcement of the current requirements is complex;

(4) Reviews of nuclear power plant licensees' controls on work hours have repeatedly identified practices that are inconsistent with the NRC's Policy on Worker Fatigue, including excessive work hours and the overuse of work-hour limit deviations;

(5) The current regulatory framework is comprised of requirements that are inadequate and incomplete for effective fatigue management;

(6) Ensuring effective management of worker fatigue through rulemaking would substantially enhance the effectiveness of FFD programs, but additional orders are not presently warranted to ensure adequate protection of public health and safety or the common defense and security; and

(7) Preventing the fatigue of workers in safety-critical positions through regulation is consistent with practices in foreign countries and other industries in the U.S.

The proposed requirements also would apply to C/Vs who implement FFD programs or program elements, to the extent that nuclear power plant licensees rely upon those C/V FFD

programs or program elements to meet the requirements of this part. This proposed provision would permit licensees to rely on a C/V's fatigue management program, consistent with the permission for licensees to rely on licensee-approved FFD programs and program elements in current §26.23(a), as retained in proposed §26.3 [Scope].

Proposed Subpart I would not apply to the materials licensees who are otherwise subject to Part 26 (see proposed §26.3 [Scope]) for two reasons. First, NRC analyses have indicated that significant offsite radiological exposure is not a realistic accident consequence at a materials facility that is subject to Part 26 regulations because of the nature of the radioactive materials that are involved and the multiple layers of controls that are required under NRC regulations. Second, there is no evidence of excessive overtime use by the materials licensees who are subject to Part 26. Therefore, applying the requirements in Subpart I to these licensees would be unnecessary. The costs associated with establishing work hour controls to meet the proposed Subpart I requirements would not be commensurate with a corresponding benefit to the protection of public health and safety and the environment. However, requirements to prevent fatigue from adversely affecting the job performance of security personnel at materials facilities may provide a substantial enhancement to the security of these facilities. In SRM-COMSECY-04-0037, dated September 1, 2004, the Commission determined that FFD enhancements related to the fatigue of security force personnel at Independent Spent Fuel Storage Installations, Decommissioning Reactors, Category I Fuel Cycle Facilities, Gaseous Diffusion Plants, and the Natural Uranium Conversion Facility should be pursued as a separate rulemaking activity with additional stakeholder interactions. That activity is scheduled to begin in FY 2006. Publication of a proposed rule related to fatigue of security forces for these materials facilities would not occur until the final rule is published from this rulemaking.

Section 26.197 General provisions

Proposed §26.197 [General provisions] would be added to establish fatigue management requirements for licensees' FFD programs. The general provisions in this section would establish requirements for licensees' fatigue management policies, procedures, training, examinations, recordkeeping, and reporting. The NRC's objective in establishing these general provisions would be to facilitate integrating fatigue management into licensees' FFD programs, as discussed in Section IV. D.

Proposed §26.197(a) [Policy] would be added to require each licensee to have a written policy statement that describes its management's expectations and methods for managing fatigue to ensure that fatigue does not adversely affect any individual's ability to safely and competently perform his or her duties. The NRC believes that the responsibility for ensuring that each individual is fit to safely and competently perform his or her duties is shared between the licensee and the individuals who perform duties on the licensee's behalf. Therefore, the proposed rule would require each licensee's FFD policy to set forth the licensee's fatigue management policy, so that individuals who are subject to it will be aware of and may comply with the fatigue management requirements for which they will be held accountable. The proposed rule would require each licensee to incorporate the fatigue management policy statement into the written FFD policy that would be required under proposed §26.27(b). As discussed with respect to proposed §26.27(b), the proposed rule would require the policy statement to be clear, concise, and readily available, in its most current form, to all individuals who are subject to the policy.

The NRC's past experience with worker fatigue, such as that documented in NRC Regulatory Issue Summary (RIS) 2002-007, Clarification of NRC Requirements Applicable to Worker Fatigue and Self-declarations of Fitness-For-Duty, dated May 10, 2002, (referred to in

this document as RIS 2002-007), indicates that there is a need for individuals to clearly understand their fatigue management responsibilities and those of the licensee. These responsibilities would include the individual's responsibility to report FFD concerns, including concerns related to the impact of fatigue on the individual's ability to safely and competently perform his or her job duties, as well as concerns related to others, and the licensee's responsibility to assess such fatigue-related FFD concerns. Further, the proposed rule would not prohibit licensees from imposing sanctions on individuals for failing to comply with the portions of the licensees' fatigue management policies that assign certain responsibilities to individuals. For example, some licensees may impose sanctions on an individual who fails to seek recommended treatment for a sleep disorder that, as part of a determination of fitness performed in accordance with proposed §26.189 [Determination of fitness], a healthcare professional has determined is adversely affecting the individual's job performance and potentially could be medically resolved. The proposed rule would not establish minimum sanctions for individual failures to comply with such fatigue management requirements because the reasons that an individual may report to work in a fatigued state are varied and often highly personal. Rather, the NRC prefers to permit licensees and the appropriate healthcare professionals to respond to such circumstances on a case-by-case basis. However, in order to protect individuals' rights to due process under the rule, it would be necessary for licensees' fatigue management policies to communicate any sanctions that a licensee may impose on an individual for failing to comply with the policy's requirements.

Proposed §26.197(b) [Procedures] would be added to require licensees to develop, implement, and maintain procedures to implement the fatigue management policy that would be required under proposed §26.197(b). Procedures would be necessary to ensure that licensees' fatigue management programs are properly and consistently implemented.

Proposed §26.197(b)(1) would require licensees to develop, implement, and maintain procedures that describe the process to be followed any time an individual who is subject to the licensee's FFD program reports to a supervisor that he or she is unfit for duty because of fatigue (i.e., makes a self-declaration). The NRC previously noted in RIS 2002-007 that self-declaration is an important adjunct to behavioral observation in meeting the requirements of the performance objective in current §26.10(b) [as retained in proposed §26.23(c)], which is "to provide reasonable measures for the early detection of persons who are not fit to perform the job duties that require them to be subject to this part." Because individuals are the first line of defense against the potential for fatigue-related impairment to adversely affect their job performance, it is essential that all individuals who are subject to a licensee's FFD program understand when and how to make a self-declaration that they are unfit for duty. Individuals must also understand how the licensee's response to a worker's self-declaration will differ from a licensee's response to an individual's general statement of fatigue (e.g., casually commenting to a co-worker, "I'm really tired today"), if the individual does not express a concern that is specific to his or her fitness for duty (e.g., formally stating to a supervisor, "I am too tired right now to check these valve lineups accurately").

Proposed §26.197(b)(1)(i) would require the licensee's self-declaration procedure to describe the responsibilities of individuals and licensees and the actions they must take with respect to an individual's self-declaration of fatigue. The NRC has considered industry experience with individuals refusing to report to work on the basis that they were too tired, and has concluded that detailed procedures are necessary to specify: (1) the individual's responsibility to be available at work for a fatigue assessment, which must be conducted face-to-face under proposed §26.201(b) for the reasons discussed with respect to that paragraph; (2) the individual's responsibility to cooperate with the fatigue assessment process by providing

the necessary information [see the discussion of proposed §26.201(c)(2)]; and (3) the licensee's responsibility for conducting a fatigue assessment in response to an individual's self-declaration, as required under proposed §26.201(a)(2), to determine whether, and under what controls and conditions, if any, the individual may be permitted or required to work.

Proposed §26.197(b)(1)(ii) would require the licensee's self-declaration procedure to describe requirements for establishing controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit for duty as a result of fatigue. This portion of the procedure would be necessary to ensure correct and consistent implementation of the requirements in proposed §26.201(b), which would require that a supervisor or staff member of the FFD program must conduct the fatigue assessment and make a determination whether, and under what conditions, an individual who has self-declared may be returned to duty. For example, the licensee's procedure would provide guidance on establishing appropriate controls and conditions under which an individual could be permitted or directed to return to work after declaring that he or she is unfit because of fatigue. Controls and conditions may include, but would not be limited to: (1) controls on the type of work to be performed (e.g., physical or mental, tedious or stimulating, individual or group, risk-significant or not); (2) the required level of supervision (continuous or intermittent) and other oversight (e.g., peer checks, independent verifications, quality assurance reviews, and operability checks); and (3) the need to implement fatigue countermeasures (e.g., naps, rest breaks). The purpose of the controls and conditions would be to mitigate the risks to public health and safety or the common defense and security that a fatigue-induced human error could pose, as discussed in Section IV. D.

Proposed §26.197(b)(1)(iii) would be added to require licensee procedures to describe the processes to be followed if an individual disagrees with the results of a fatigue assessment

that was conducted in response to the individual's self-declaration. These procedures would address situations in which the individual disagrees with the licensee's determination either that the individual is capable of performing work safely (with appropriate controls and conditions, if necessary) or that the individual cannot safely be permitted to perform the job duties listed in proposed §26.199(a) because of fatigue. For example, the licensee's procedure may refer an individual who disagrees with the outcome of the fatigue assessment to the bargaining unit to initiate a grievance process, the employee concerns program, or the corrective action program.

The proposed rule would add this requirement for several reasons. First, in RIS 2002-007, the NRC documented concerns associated with past instances of self-declaration. The NRC believes that these instances indicated the need for licensees to describe the processes to be followed if an individual disagrees with the results of a fatigue assessment following a self-declaration. In addition, at the public meetings discussed in Section V, several stakeholders requested that this provision be added to the proposed rule to ensure that individuals have recourse if they disagree with the results of a fatigue assessment that was conducted in response to a self-declaration. Some of the stakeholders expressed a concern for the potential impact on public health and safety if an individual is convinced that he or she is too fatigued to perform work safely but the licensee requires the individual to work. Other stakeholders expressed concerns that an individual may experience adverse employment and financial consequences if he or she is prevented from working because of fatigue.

The NRC concurs that licensee policies and procedures related to implementing the requirements of this proposed subpart must address these potential issues in order to protect the due process rights of individuals who would be subject to the rule. However, the proposed rule would not establish specific requirements for the process(es) to be followed in such instances for two reasons: (1) licensees have already implemented a number of processes for

addressing similar safety and employment issues that provide appropriate mechanisms for resolving fatigue-related issues, and (2) there is such a wide variety of possible issues that may arise that establishing one mechanism in the proposed rule could not be expected to appropriately address them all. Therefore, the proposed rule would require licensees to have procedures for addressing situations in which an individual who has self-declared disagrees with the outcome of a fatigue assessment, but would not require a new process nor specify the required characteristics of the process(es) the licensees would use.

Proposed §26.197(b)(2) would be added to require that licensee procedures must describe the process for implementing the work hour controls that would be required under proposed §26.199 [Work hour controls]. For example, the procedures would detail individual and organizational responsibilities and requirements, including items such as: scheduling; tracking and calculating work hours; granting waivers of the individual work hour controls; reviewing the implementation of the work hour controls; documenting the results of the reviews; and implementing any necessary corrective actions. These procedures would be necessary to ensure that individuals understand the work hour controls to which they are subject and that licensees consistently implement the work hour controls required in proposed §26.199 and as the NRC intends.

Proposed §26.197(b)(3) would be added to require that licensee procedures must describe the process(es) to be followed in conducting a fatigue assessment, as required under proposed §26.201(a). The proposed procedures would establish the methods through which the licensee would determine whether an individual who may be fatigued will be permitted or required to perform work and whether controls and conditions are necessary for the individual to be able to perform work safely and competently. The licensee's procedure would address fatigue assessments that are conducted following an individual's self-declaration, an event, for

cause, or to reassess an individual after returning the individual to work despite a self-declaration of fatigue [the situations in which the proposed rule would require licensees to conduct fatigue assessments are discussed with respect to proposed §26.201(a)]. Because of the potentially subjective and personal nature of the fatigue assessment task and the potential for conflict and sanctions (e.g., if an individual is determined to have been asleep while on duty), comprehensive procedures would be necessary to ensure consistent implementation of the fatigue assessment requirements in proposed §26.201 [Fatigue assessments]. Therefore, the NRC expects that these procedures would describe measures to ensure that fatigue assessments: (1) are performed by properly trained personnel; (2) are free of bias; (3) methodically address the factors that commonly contribute to fatigue; (4) are based on complete and accurate information; (5) protect the privacy of the individuals being assessed; (6) recognize the fact that an individual may be fatigued and unfit for duty even though he or she has not exceeded the work-hour limits; (7) are thoroughly documented; and (8) are reviewed, as required by proposed §26.199(j)(1). These procedures would be necessary to implement the proposed requirements in this subpart and protect the due process and privacy rights of individuals, consistent with Goal 7 of this rulemaking.

Proposed §26.197(b)(4) would be added to require licensees to describe in a procedure the sanctions they may impose on individuals, if any, following a fatigue assessment (e.g., termination or leave without pay). During the public meetings discussed in Section V, several industry representatives indicated that licensees may rely upon the results of a fatigue assessment as the basis for determining that an individual has not met management expectations for maintaining his or her fitness for duty. Although the NRC neither endorses nor prohibits the imposition of sanctions in cases of fatigue, licensees have an obligation to provide due process to individuals who are subject to their FFD policy. For this reason, procedures

would be necessary to ensure that licensees fully disclose the conditions under which sanctions would be considered; the nature of the possible sanctions; and the process for administering and imposing the sanctions, including management's expectations and the individual's right to a review of the determination that he or she has violated the FFD policy, as required under proposed §26.39 [Review process for fitness-for-duty policy violations].

Proposed §26.197(c) [Training and examinations] would establish additional fatigue-related training and examination requirements, in addition to those required under proposed §26.29(a) and (b). Several of the knowledge and abilities (KAs) requirements that are listed in proposed §26.29(a) would ensure that individuals are familiar with a licensee's or other entity's fatigue policies and procedures, which may include the consequences of violating them under proposed §26.29(a)(1), and individuals' and others' responsibilities under the licensee's FFD program in proposed §26.29(a)(2) and (a)(3). However, individuals who would be subject to Subpart I should also have a working-level knowledge of specific, fatigue-related topics that may facilitate personal decisions and actions that are consistent with the objective of preventing, detecting, and mitigating the adverse effects of fatigue on worker job performance. Individual workers typically do not possess these KAs without training (Folkard and Tucker, 2003; Knauth and Hornberger, 2003; Monk, 2000). Therefore, the proposed rule would require licensees to address the topics specified in proposed §26.197(c)(1) and (c)(2) in their FFD training and testing programs.

Proposed §26.197(c)(1) would require FFD training and examinations to ensure that individuals who are subject to the proposed subpart understand the contributors to worker fatigue, circadian variations in alertness and performance, indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures. Examples of topics that licensee training and examinations would

address that are related to this KA would include, but are not limited to: (1) the principal factors that influence worker fatigue; (2) knowledge that a worker's ability to perform and remain alert is influenced by physiological changes that follow a daily pattern; (3) the time periods during which workers are most likely to exhibit degraded alertness and performance; (4) the principal symptoms of common sleep disorders (e.g., sleep apnea and insomnia) and the conditions that can contribute to their onset; (5) the methods for optimizing sleep periods on a shiftwork schedule; and (6) how to safely and effectively counteract fatigue with measures such as caffeine and strategic napping. Knowledge of these topics is necessary to ensure that individuals are able to: (1) self-manage fatigue that is caused by shiftwork and factors other than work hours; (2) take actions to maintain their alertness at work; and (3) recognize and seek treatment for sleep disorders that might be creating or exacerbating their own fatigue. In addition, training in methods for coping with the challenges of shiftwork may contribute to a more stable workforce by reducing worker turnover. A survey by Circadian Technologies Incorporated of 550 facilities in the U.S. and Canada found that turnover at facilities with operations extending beyond 7a.m. to 7 p.m. averaged 10 percent in 2003, compared with 3.4 percent in all U.S. companies. Facilities offering no training on specific coping strategies had an average turnover rate of 11.4 percent, compared to 7.6 percent for facilities that offered such training to their employees, and 2.9 percent for those offering the training to employees and their family members (Circadian Technologies Incorporated, 2004).

Proposed §26.197(c)(2) would require FFD training and examinations to ensure that individuals who are subject to proposed Subpart I have the ability to identify symptoms of worker fatigue and contributors to decreased alertness in the workplace. Examples of topics that are related to this KA would include, but are not limited to: (1) behavioral symptoms of fatigue (e.g., yawning, red-eyes, prolonged or excessive blinking, irritability); (2) task conditions

that may contribute to degraded alertness and increased fatigue (e.g., repetitive tasks, tasks with high cognitive or attentional demands, tasks that require the individual to be sedentary, tasks that limit social interaction); and (3) environmental conditions that may contribute to degraded alertness and increased worker fatigue (e.g., high heat and humidity, low lighting, and low frequency noise/white noise). Requiring individuals to be trained on this KA would be necessary to ensure that an individual is able to determine when it is appropriate to self-declare that he or she is unfit for duty because of fatigue, as permitted under proposed §§26.199(e) and 26.201(a)(2), and identify other individuals who are exhibiting indications of fatigue through behavioral observation to determine when it is appropriate to report an FFD concern about another individual, as required under proposed §26.33 [Behavioral observation].

Proposed §26.197(d) [Recordkeeping] would be added to establish recordkeeping requirements related to the implementation of proposed Subpart I. Specifically, proposed §26.197(d)(1) would require licensees to retain records of the number of hours worked by individuals who are subject to the work hour controls established in proposed §26.199 [Work hour controls]; proposed §26.197(d)(2) would require licensees to retain records of the number of waivers they have granted and the bases for those waivers; proposed §26.197(d)(3) would require licensees to retain documentation of the work hour reviews that would be required under proposed §26.199(j)(3); proposed §26.197(d)(4) would require retaining documentation of any fatigue assessments that would be conducted, as required by proposed §26.201(g); and proposed §26.197(d)(5) would require licensees to retain documentation of each job duty group's collective work hours. The proposed rule would establish these recordkeeping requirements for four reasons: (1) these records would be necessary to ensure that documentation of the licensee's fatigue management program is retained and available for NRC inspectors to verify that licensees are complying with the proposed work hour controls,

and waiver and fatigue assessment provisions; (2) the documentation may be necessary for a review process under proposed §26.39 [Review process for fitness-for-duty policy violations] or in legal proceedings related to a determination that an individual has violated the fatigue provisions of an FFD policy; (3) the documentation would be necessary to perform the trending and self-assessments that would be required under proposed §26.199(j) [Reviews]; and (4) the documentation would be necessary to meet the reporting requirements in proposed §26.197(e) [Reporting]. In order to ensure that the records remain available for NRC inspections and for the review process or legal proceedings, the proposed paragraph would require licensees to retain these records for 3 years or until the completion of any related legal proceedings, whichever is later.

Proposed §26.197(e) [Reporting] would be added to require licensees to report to the NRC certain data related to their fatigue management programs as part of the annual FFD program performance report, which licensees would be required to submit under proposed §26.217 [Fitness-for-duty program performance data]. The proposed rule would require licensees to include the following information in the annual report: (1) information on the number of waivers granted from work hour controls from the previous calendar year; (2) the collective work hours for any job duty group whose average work hours exceeds 48 hours per week; and (3) the number of fatigue assessments conducted during the year, the management actions that resulted, and the conditions under which the fatigue assessments were conducted. The NRC would use the information in these annual reports for several purposes.

The primary reason for requiring licensees to submit this information annually would be that, as discussed in Section IV. D, certain nuclear power plant licensees have permitted individuals to work hours that are significantly in excess of those intended under the NRC's Policy on Worker Fatigue and abused the waiver provisions of the Policy by granting blanket

waivers to large groups of plant personnel for extended periods of time. It is the intent of the requirements in proposed Subpart I to ensure that such abuses do not recur under the proposed rule. However, the NRC does not have the resources to inspect every licensee's fatigue management program each year and collect this information by relying solely on NRC inspection personnel. Therefore, the proposed requirement for licensees to submit this information would be necessary to ensure that it would be available for the NRC's review and evaluation to identify licensees whose fatigue management programs do not appear to be meeting the objectives of this proposed subpart.

In addition, the proposed reports would permit the NRC to more efficiently focus its inspection resources on those licensees' fatigue management programs that do not appear to be meeting the objectives of this proposed subpart, and thereby maximize the efficiency of the inspection process. Obtaining information about significant fatigue-management issues and events (e.g., events resulting in fatigue assessments, or plant events occurring while work hour limits are waived) would permit the NRC to evaluate situations that may indicate inadequate licensee performance. Inadequate licensee performance may require action by the NRC staff to ensure that public health and safety and the common defense and security are not compromised.

The NRC also requires the information to: (1) track the effectiveness of the requirements of proposed Subpart I in controlling the fatigue of nuclear power plant workers; (2) assess whether the objectives of the proposed requirements are being achieved; and (3) determine whether any further changes to the requirements are necessary to ensure that worker fatigue is managed consistent with the intent of the provisions. As a hypothetical example, if analyses of the data obtained from the annual reports show that, across the industry, (1) licensees generally grant significantly more waivers for operations personnel than

any other job duty groups, (2) operations job duty groups exceed the 48-hour per person per week work group average limit significantly more often than any other job duty groups, and (3) operations personnel are subject to more for-cause fatigue assessments than individuals in any other work groups, the NRC may determine that it is necessary to further evaluate the causes for these findings and potentially revise the requirements of Subpart I as they relate to the operations job duty group.

In summary, because the information that licensees would be required to report would be central to assessing licensee performance, efficiently allocating NRC inspection resources, and evaluating the effectiveness of the proposed Subpart I requirements, the reporting burden that these requirements would impose on licensees is warranted. However, the NRC expects that the additional burden associated with the proposed requirements for licensees to add this information to their annual reports would be minimal because proposed §26.199(j) [Reviews] would require licensees to aggregate and review this information after each averaging period for the reasons discussed with respect to that proposed provision. Therefore, the proposed requirement to include the information in the annual FFD program performance report would not impose a significant additional burden.

Proposed §26.197(e)(1) would require licensees to provide the NRC with an annual summary of the number of instances during the previous calendar year in which the licensee waived each of the work hour controls specified in proposed §26.199(d)(1) and (d)(2) for each of the job duty groups listed in proposed §26.199(a). (Waivers of the work hour controls in proposed §26.199(d)(1) and (d)(2) would be permitted under proposed §26.199(d)(3) for the reasons discussed with respect to proposed §26.199(d)(3).) For example, if a licensee granted 10 waivers to one operator that permitted him or her to work 18 hours in a 24-hour period [see proposed §26.199(d)(1)(i)] on 10 separate occasions during the calendar year, the licensee

would report that the work hour limit in proposed §26.199(d)(1)(i) was waived 10 times in the operations job duty group that year. The job duty groups who would be subject to work hour controls are discussed with respect to proposed §26.199(a). Similarly, if the licensee granted one waiver to each of 10 different operators to permit the operators to work 18 hours in a 24-hour period, the licensee would also report that the work hour limit in proposed §26.199(d)(1)(i) was waived 10 times in the operations job duty group that year. As another example, if the licensee permitted an operator to work 18 hours in a 24-hour period three times in a year, another operator to work 80 hours in a 7-day period, and another operator to take a rest break of only 6 hours between shifts, then the licensee would report that the operations job duty group was granted three waivers of proposed §26.199(d)(1)(i), one waiver of proposed §26.199(d)(1)(iii), and one waiver of proposed §26.199(d)(2)(i) for the year.

As a fourth and more complex example, if a licensee permitted an operator who normally works 12-hour shifts to work a seventh 12-hour consecutive shift, followed by a second waiver on the eighth day to work another 12-hour shift, then the licensee would report multiple waivers. In this example, on the seventh day, the licensee would grant one waiver of proposed §26.199(d)(1)(iii) for working 84 hours in a 7-day period and one waiver of proposed §26.199(d)(2)(ii) for not receiving the required 24-hour break in a 7-day period. On the eighth day, the individual would be granted those same two waivers again. So, the licensee would report the instances on the seventh and eighth days as two waivers of proposed §26.199(d)(1)(iii) and two waivers of proposed §26.199(d)(2)(ii). This example presumes that the individual received the 48-hour break required by proposed §26.199(d)(2)(iii) within the 6 days preceding day 1, otherwise additional waivers from that provision would also be required and reported.

The proposed rule would also establish additional requirements related to aggregating and reporting the waiver data, as follows:

Proposed §26.197(e)(1)(i) would require licensees to include in the annual report only those waivers under which work was actually performed. The proposed rule would add this provision because it may sometimes be unnecessary for individuals to work the extended hours for which a licensee planned when granting a waiver. Licensees may anticipate that it will be necessary to waive one or more work hour control in proposed §26.199(d)(1) and (d)(2) in order to complete a task, and so implement the process specified in proposed §26.199(d)(3) for granting waivers. However, on some occasions, the work will be finished sooner than the licensee anticipated, with the result that the waiver was granted but no-one was required to work an extended work period. The proposed rule would require licensees to exclude waivers under which no work was performed from the annual report because the granting of a waiver provides would provide no meaningful information about the licensee's management of fatigue during extended work periods.

In addition, proposed §26.197(e)(1)(ii) would require licensees to report all waivers granted of each of the work hour controls in proposed §26.199(d)(1) and (d)(2) for each job duty group, to include all of the waivers that were granted for those instances in which a single extended work period required waiving more than one of the work hour controls. For example, if a component failure creates a condition adverse to safety, the licensee may determine that a waiver of the work hour controls for a four-person crew of maintenance technicians would be necessary to resolve the adverse safety condition in a timely manner. Assuming that the results of fatigue assessments of the individuals involved indicated that they were able to continue working, the licensee may decide to waive two of the limits on individual work hours in proposed §26.199(d)(1) for each of four crew members to enable them to complete the repair.

Therefore, depending upon the actual circumstances, proposed §26.199(e)(1)(ii) would require the licensee's annual summary to report, for example, that waivers were granted to four maintenance technicians of the "16 work hours in any 24-hour period" individual work hour limit in proposed §26.199(d)(1)(i) as well as four waivers of the "26 work hours in any 48-hour period" requirement in proposed §26.199(d)(1)(ii). Although the maintenance crew may have worked for only a single extended work period, the licensee's annual summary would include all eight of the waivers that the licensee would grant in this example.

The waiver data that licensees would be required to report to the NRC under proposed §26.197(e)(1)(i) and (e)(1)(ii) would be important because waivers represent "assumed risk." For example, as discussed in Section IV. D, fatigued workers have impaired cognitive functioning, including difficulties in maintaining attention and alertness. If a licensee permits an individual to work extended hours that cause the individual to become fatigued, the individual may experience momentary lapses in attention or degraded decision-making from fatigue that could cause him or her to commit errors that may pose risks to public health and safety and the common defense and security. These performance degradations can be mitigated by establishing controls and conditions under which the individual is permitted to work, as would be required under proposed §26.201(e). However, controls and conditions cannot eliminate errors altogether and would reduce, but not eliminate, the potential risks to public health and safety or the common defense and security from fatigue-induced errors. The more often that a licensee permits individuals to exceed work hour limits, the more risk from fatigue-induced errors that a licensee would be assuming. The risk of fatigue-induced errors increases further when an individual is permitted to exceed more than one of the work hour limits in proposed §26.199(d)(1)(i)–(d)(1)(iii) because of the potential for combined effects of both acute and cumulative fatigue. Any waivers from the rest breaks that would be required under proposed

§26.199(d)(2)(i)–(d)(2)(iii) would also contribute to the accumulation of a sleep deficit, especially when inadequate rest breaks are combined with long work hours. Repeated and continual use of waivers may indicate a staffing or other programmatic weakness at a site that warrants additional inspection resources. Therefore, the NRC considers the number of waivers granted from the work hour limits to be a key element of FFD program performance.

During the September 14, 2004 public meeting, NEI commented that the number of waivers granted would not give meaningful information about the health of a licensee's program. However, as discussed in Section IV. D, certain nuclear power plant licensees have granted thousands of waivers each year under the current Policy on Worker Fatigue. This level of waiver use is inconsistent with the intent of the NRC's Policy and provides a clear indication that these licensees have not been effectively managing fatigue. If a licensee continued to grant thousands of waivers each year under the requirements of this proposed subpart, the sheer number of waivers granted in this case would provide meaningful information about the licensee's fatigue management program as well as the effectiveness of these proposed requirements. In less extreme circumstances, the NRC concurs that a simple summary of the number of waivers granted during the year would not provide sufficient information for the NRC to evaluate a licensee's practices with respect to granting waivers. It is for this reason that the proposed rule would require licensees to report additional information about their fatigue management practices in the annual summary report under proposed §26.197(e)(2) and (e)(3) to provide the contextual information necessary to properly interpret the waiver data that proposed §26.197(e)(1) would require. When considered in conjunction with number of instances in which collective work hour limits [in proposed §26.197(e)(2)] are exceeded and the number of fatigue assessments that a licensee conducts each year and their outcomes [in proposed §26.197(e)(3)], the number of waivers granted in a year provides an important

indicator of the health of the licensee's fatigue management program. Therefore, the proposed requirement for licensees to report the number of waivers granted each year would be necessary to: (1) evaluate the effectiveness of the more stringent requirements for granting waivers in proposed §26.199(d)(3), which will be discussed further with respect to that paragraph; and (2) monitor the ongoing effectiveness of licensees' fatigue management programs, when considered together with the other information that licensees would be required to report in this proposed paragraph.

Proposed §26.197(e)(2) would be added to require licensees to report the collective work hours of any job duty group listed in proposed §26.199(a) that exceeded the applicable collective work hour limits in any averaging period during the previous calendar year under the conditions specified in proposed §26.199(f)(3) and (f)(5). As discussed with respect to proposed §26.199(f)(3), the proposed rule would permit a job duty group's collective work hours to exceed 48 hours per person per week during one averaging period if all of the following conditions are met: (1) the circumstances that caused the group's collective work hours to exceed 48 hours per person per week could not be reasonably controlled; (2) the group's collective work hours did not exceed 54 hours per person per week; and (3) the additional work hours were worked only to address the circumstances that the licensee could not have reasonably controlled. Proposed §26.199(f)(5) would also permit licensees to exceed any of the collective work hour limits in proposed §26.199(f), if the licensee receives prior approval from the NRC of a written request to exceed the work hour limits.

Proposed §26.197(e)(2) would require licensees to report the collective work hours of any job duty group whose collective work hours exceeded the specified collective work hour limits during the previous year because this information would be necessary for the NRC to monitor the effectiveness of licensees' ongoing compliance with the proposed collective work

hour limits that would be established in proposed §26.199(f) [Collective work hour limits]. The number of times that collective work hour limits are exceeded in a year would be indicative of a licensee's effectiveness in managing the fatigue of its workers who would be subject to the proposed requirements of proposed §26.199. Exceeding the collective work hour limits on repeated occasions may indicate a programmatic weakness that would necessitate further NRC inspection activities to address questions related to, for example, the adequacy of licensee staffing within specific job duty groups, overall management of cumulative fatigue, or corrective actions for fatigue management weaknesses. Collectively, information concerning instances in which collective work hour limits are exceeded, in conjunction with information concerning the number of waivers granted [in proposed §26.197(e)(1)] and the number of fatigue assessments that a licensee conducts each year and their outcomes (in proposed §26.197(e)(3)), provide a strong indicator of the health of the licensee's fatigue management program.

The NRC believes that the additional burden of including these instances in the annual report to be minimal, as the intent of the provisions is that the collective work hour limits in proposed §26.199(f) would be exceeded only under very infrequent circumstances. Further, the NRC considers the burden to be significantly outweighed by the need to effectively use NRC inspection resources. The proposed paragraph would limit the reporting of occasions on which a job duty group exceeds collective work hour limits to those specified in proposed §26.199(f)(3) and (f)(5) because the proposed rule would establish other reporting requirements for other instances in which a job duty group's collective work hours may exceed the proposed collective work hour limits, as discussed further with respect to the relevant provisions.

Proposed §26.197(e)(3) would be added to require that licensees include in the annual report the number of fatigue assessments conducted, the conditions under which each assessment was conducted [i.e., whether the assessment was conducted for-cause, for a self-

declaration, post-event, or as a followup, as described in proposed §26.201(a)(1)–(a)(4)], and the management actions that resulted from each assessment. The NRC considers that the reporting of the fatigue assessments and their outcomes is similar to the reporting of drug and alcohol tests results, which is also a part of the annual report. For example, the NRC views the number of for-cause drug and alcohol tests that a licensee conducts each year to be one indicator of the health of the licensee's behavioral observation program and its effectiveness in meeting the rule's performance objective, in proposed §26.23(c), to provide for the early detection of individuals who are not fit to perform the job duties that require them to be subject to this part. The NRC would similarly view the number of for-cause fatigue assessments that a licensee conducts each year to be one factor indicating the health of the licensee's behavioral observation and self-declaration processes with respect to fatigue.

Collectively, the reporting of waivers that would be required in proposed §26.197(e)(1), the number of instances in which a licensee exceeds the 48-hour per person collective work hour limit that would be required in proposed §26.197(e)(2), and the number of fatigue assessments conducted and their outcomes that would be required in §26.197(e)(3), would provide important information concerning the effectiveness of fatigue management at a licensee site. Together, the proposed reports would permit the NRC to: (1) efficiently monitor the ongoing effectiveness of licensees' fatigue management programs by providing interpretable data; (2) efficiently allocate inspection resources; (3) track the effectiveness of the requirements of proposed Subpart I in controlling the fatigue of nuclear power plant workers; (4) assess whether the objectives of the proposed rule are being achieved; and (5) determine whether any further changes to the requirements would be necessary to ensure that worker fatigue is managed consistent with the intent of the provisions.

Section 26.199 Work Hour Controls

Proposed §26.199 [Work hour controls] would be added to establish controls on the work hours of select individuals who are subject to nuclear power plant licensees' FFD programs, as follows:

Proposed §26.199(a) [Individuals subject to work hour controls] would be added to establish the scope of individuals who would be subject to the work hour controls in proposed §26.199. These individuals would be subject to the proposed work hour controls, in addition to the proposed training, behavioral observation, and self-declaration requirements of Subpart I that would apply to all individuals who are subject to nuclear power plant licensees' FFD programs. In determining the scope of personnel who would be subject to the proposed work hour controls, the NRC considered the burdens on individuals and licensees associated with the practical control of work hours in conjunction with the potential for individuals' work activities to affect public health and safety or the common defense and security if their performance is degraded by fatigue. The NRC also considered the nature of these individuals' work activities and work environments relative to their potential to induce or exacerbate fatigue (e.g., whether the work is monotonous or the environment is not stimulating), the risk significance of the work, and the potential for other controls to prevent or mitigate the consequences of a fatigue-related error. As a result of these deliberations, the proposed rule would require that individuals who perform the types of job duties specified in proposed §26.199(a)(1)–(a)(5) must be subject to the proposed work hour controls.

Proposed §26.199(a)(1) would require that individuals who operate or provide onsite direction of the operation of systems and components that "a risk informed evaluation process has shown to be significant to public health and safety" must be subject to the proposed work hour controls in this section. In order to implement the proposed work hour controls, nuclear

power plant licensees would be required to delineate the operations personnel who would be subject to the proposed work hour controls, based upon the risk significance of the safety systems and components (SSCs) being operated, including, at a minimum, personnel who are performing activities on SSCs that are determined to be significant to public health and safety. To delineate the scope of the operations job duty group, licensees could use, for example, the risk significance determination process and criteria that they currently use to meet the requirements of §50.65(a)(4) of this chapter for assessing and managing the risk associated with maintenance activities. The work hour controls of proposed §26.199 would typically apply to individuals who are operating or directing, while on site, the operation of SSCs that are included within the scope of an assessment required by §50.65(a)(4). Therefore, the proposed work hour controls would apply to the individuals who most directly affect the operation of SSCs that are most important to the protection of public health and safety. Controlling the work hours of these individuals would achieve the NRC's objective to minimize the potential for fatigue-related errors in operating these risk-significant SSCs.

Licensed operators, who perform the job duties specified in proposed §26.199(a), are responsible for correctly performing actions that are necessary for the safe operation of nuclear power plants and the mitigation of accidents at these facilities. These responsibilities include monitoring the plant for off-normal conditions and taking appropriate actions to prevent these conditions from challenging the reactor core, safety systems, and fission product barriers. The importance of licensed operator actions to the protection of public health and safety is reflected in the 10 CFR Part 55 requirements that are applicable to these individuals, including specific licensing, examination and testing, requalification, and FFD requirements. In addition to performing actions that are necessary for accident mitigation, operator actions, if performed incorrectly, can be accident initiators. The effects of fatigue on decision-making, risk-taking,

communications, and other key skills were discussed in Section IV. D. Fatigued operators have an increased potential to commit errors, increasing the probability of component failures, system misalignments, and incorrect execution of accident mitigation strategies. Operator actions are highly dependent on cognitive skills (e.g., attention, decision-making) that are susceptible to fatigue, and operators are frequently exposed to conditions that can induce fatigue (e.g., long work hours, shiftwork). The NRC highlighted this concern in 1982 by issuing its Policy on Worker Fatigue. The policy specifically addressed the need for "controls to prevent situations where fatigue could reduce the ability of operating personnel to keep the reactor in a safe condition."

Despite the NRC's Policy on Worker Fatigue and subsequent technical specifications to limit operator work hours, an NRC staff review of technical specification implementation from 1997–1999 found that a significant percentage of licensed and non-licensed operators worked more the 600 hours of overtime in a year (SECY-01-0113, Attachment 1). This level of overtime is two to three times the level that is permitted for operations personnel at some foreign nuclear plants and twice the level recommended by a 1985 expert panel (NUREG/CR-4248). In addition, the NRC staff has noted that some licensees appeared to be abusing the authority to permit deviations from the technical specification limits on working hours, including deviations for operators. For example, data provided by NEI on August 29, 2000, from J. W. Davis, NEI, to G. T. Tracy (ADAMS Accession No. ML003746495), indicated that during 37 refueling outages conducted in 1999, more than 1,800 deviations were authorized for licensed operators and more than 1,100 deviations were authorized for non-licensed operators. This frequency of deviations is inconsistent with the intent of the NRC's Policy on Worker Fatigue that deviations should be authorized only for "very unusual circumstances." The failure of some licensees to limit the work hours of operations personnel, considered together with the risk

significance of the activities performed by operators, indicates the need for more readily enforceable work hour limits for operators whose job duties are important to protect public health and safety.

Further, the work hour controls in proposed §26.199 would also apply to individuals who direct risk-significant operations onsite. These individuals would include management on shift, such as shift operations management or special outage managers if those individuals provide direction to operators. Individuals to whom the work hour controls would apply also include engineers who provide onsite technical direction to operations, such as test directors or reactor engineers. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decision-making, communications) and are susceptible to fatigue-induced errors, as described in Section IV. D. Incorrect technical direction provided to operators can significantly challenge licensed operators and increase the possibility of errors or events, especially when the direction is provided by an individual who supervises the operators, or an individual who the operator reasonably expects to have specialized technical knowledge of the system or component being operated.

Proposed §26.199(a)(2) would be added to require the control of work hours for individuals who are maintaining, or providing onsite direction of maintenance of systems and components that "a risk informed evaluation process has shown to be significant to public health and safety." To implement this proposed requirement, licensees would be required to delineate the maintenance personnel, and personnel who are directing maintenance onsite, who would be subject to the work hour controls, based upon the risk significance of the SSCs that they maintain, including, at a minimum, personnel who maintain SSCs that are determined to be significant to public health and safety. To delineate the scope of the maintenance job duty group, licensees could use, for example, the risk significance determination process and

criteria that they currently use to meet the requirements of §50.65(a)(4) of this chapter for assessing and managing the risk associated with maintenance activities. As a consequence, the work hour controls of proposed §26.199 would typically apply to individuals who are maintaining or directing onsite the maintenance of SSCs that are included within the scope of an assessment required by §50.65(a)(4). Therefore, the proposed work hour controls would apply to the individuals who most directly affect the maintenance of SSCs that are most important to the protection of public health and safety, which would achieve the NRC's objective to minimize the potential for fatigue-related errors in maintaining these risk significant SSCs.

Nuclear power plant maintenance personnel perform tasks that are often highly dependent on cognitive skills (e.g., the ability to comprehend oral and written instructions, problem-solving, communication) that are susceptible to fatigue, as described in Section IV. D. These tasks may require extensive physical effort in high heat, humidity, and noise conditions that can exacerbate fatigue. In addition, maintenance personnel are subject to the work scheduling conditions of round-the-clock operations and emergent work conditions that also can exacerbate fatigue (e.g., long work hours, unscheduled overtime, shiftwork). Compared to rested workers, fatigued maintenance personnel would have a higher probability of (1) taking longer to complete maintenance activities; (2) making errors that would increase the risk of failure of the affected SSCs to perform their function(s) or operate for their required mission time during post-maintenance testing, thus delaying their return to unrestricted service; and (3) making errors that could introduce latent defects that may not be readily detected by post-maintenance testing, but that may cause degraded reliability (i.e., degraded performance or failure of the SSCs at a later time). Collectively, the effects of fatigue on the performance of maintenance personnel have the potential to decrease the availability and reliability of SSCs that are important to the protection of public health and safety. Therefore, the proposed rule

would require these maintenance personnel to be subject to the proposed work hour limits to ensure that fatigue does not compromise their abilities to safely and competently perform their duties relative to the maintenance of these SSCs.

The proposed work hour controls would also apply to those who direct risk-significant maintenance onsite. For example, these individuals would include maintenance supervisors who provide direction to maintenance technicians, and engineers who provide onsite technical direction to maintenance crews, such as during key outage maintenance activities. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decision-making, communications) that are susceptible to fatigue, as discussed in Section IV. D. Incorrect technical direction provided to maintenance technicians can significantly challenge maintenance technicians and increase the possibility of errors or events, especially when that direction is provided by an individual who supervises them, or an individual who the maintenance technician reasonably expects to have specialized technical knowledge of the system or component being maintained.

Proposed §26.199(a)(3) would be added to require work hour controls for individuals who perform health physics or chemistry duties that are required of the on-site Emergency Response Organization (ERO) minimum shift complement. Although proposed §26.199(f) would exempt licensees from applying the work hour controls during declared emergencies, the intent of this proposed provision would be to provide reasonable assurance that the work schedules of these individuals during non-emergency conditions ensure that fatigue does not compromise their abilities to safely and competently perform their duties should an emergency occur. NUREG-1465, “Accident Source Terms for Light-Water Nuclear Power Plants,” concluded that significant fission product releases from the bulk of the fuel can occur within 30–60 minutes after the onset of an accident. As a function of the accident and its severity,

certain areas within the plant, while predictable and benign during normal operations, could present elevated levels of airborne/external radiation levels (greater that 300 Rad/hour). Additionally, industrial hazards (e.g., explosive mixtures, smoke, toxic gas, oxygen deficiency) that may be immediately dangerous to life and health (IDLH) could be present. In these circumstances, health physics technicians (HPTs) support necessary plant staff actions to assess conditions, perform search and rescue missions, and take timely mitigation actions (e.g., local manual operations by operators). The overall success of responding safely and appropriately to emergencies and the protection of public health and safety depends, in part, on the ability of HPTs to safely and competently perform their emergency response duties.

Similarly, NUREG-0654, Rev. 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," identifies the need for an on-shift chemistry/radio-chemistry emergency response capability. On-shift chemistry technician(s) provide an important component for a successful response at the onset of a radiological emergency. The independent and timely actions of the chemistry technician(s) in response to a radiological event can provide key information for assessing core status and estimating the source term of a potential release. By providing defense-in-depth support for operations personnel, chemistry technicians also assist with off-site dose calculations and ancillary radiological protection tasks, such as sampling spaces for toxic gases or explosive mixtures. Chemistry technicians may also be needed to conduct analyses for the detection of hydrogen and oxygen gas concentrations in both the reactor coolant and the containment atmosphere. These analyses support severe accident management decisions with respect to minimizing radiological release potential. As a consequence, ensuring that chemistry technicians are able to safely and competently perform their emergency response duties is

essential to the overall success of responding safely and appropriately to emergencies and to the protection of public health and safety.

Proposed §26.199(a)(4) would be added to require work hour controls for individuals who are performing the duties of a fire brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability. The proposed work hour controls would be applicable to the members of the fire brigade who are responsible for providing the control room operators and fire brigade leader with information that is critical to implementing a fire mitigation strategy to maintain safe shutdown capability for the reactor. Attachment 1 to SECY-99-140, “Recommendation for Reactor Fire Protection Inspections,” dated May 20, 1999, states that "based on IPEEE results, fire events are important contributors to the reported core damage frequency (CDF) for a majority of plants. The reported CDF contribution from fire events can, in some cases, approach (or even exceed) that from internal events." Fire brigade members must retain their cognitive abilities to be able to determine the best way to suppress a fire to prevent additional damage to safety-related equipment; evaluate equipment affected by a fire to report to control room operators concerning equipment availability; make decisions concerning smoke ventilation to prevent the fire effects from affecting other plant operations; and coordinate fire brigade activities with control room operators.

As discussed in Section IV. D, fatigue can substantially degrade an individual’s decision-making and communication abilities, cause an individual to take more risks, and maintain faulty diagnoses throughout an event. The abilities to make accurate and conservative decisions, communicate effectively, and accurately diagnose events are key to the duties of the fire brigade members who are responsible for providing the control room operators and fire brigade leader with information that is critical to implementing a fire mitigation strategy that maintains

safe shutdown capability for the reactor. Degradations of these abilities could have significant consequences on the outcome of an event involving a fire. For instance, a fatigued individual could incorrectly decide to vent smoke or toxic gas to an area required for alternate shutdown, which could prevent or impair access to equipment needed for safe shutdown of the plant. In addition, a fatigued worker could incorrectly apply the wrong fire suppressant, which could affect additional equipment in the plant. Further, impaired decision-making could lead a worker to fail to properly control flooding, which could impact other needed equipment, or to incorrectly determine whether an area contains critical equipment and improperly apply a suppressant in that area. Impaired communications could also lead to incomplete disclosure of information to licensed operators in the control room, which could adversely impact the decision-making of those operators. If information known to the impaired fire brigade member is not properly communicated, operators may not initiate appropriate actions to mitigate the fire effects, or the effects of suppressant activities, on critical equipment. As a consequence, ensuring that fire brigade members who are responsible for understanding the effects of fire and fire suppressants on safe shutdown capability are able to safely and competently perform their duties is essential to the overall success of the fire mitigation strategy and the protection of public health and safety.

Further, the NRC periodically grants exemptions from requirements in 10 CFR Part 50, Appendix R [Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979] based on protection of the levels of defense in depth listed in Section II(A) of Appendix R to Part 50, which are “To prevent fires from starting; to detect, rapidly control, and extinguish promptly those fires that do occur; to provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by the fire suppression activities will not prevent the safe shutdown of the plant.” Granting these

exemptions is often predicated on effective manual suppression of the fire by the fire brigade. Therefore, it is necessary to ensure that fire brigade members who are responsible for understanding the effects of fire and fire suppressants on safe shutdown capability remain rested and so are able to safely and competently perform their duties in plant events involving a fire.

Proposed §26.199(a)(5) would be added to require work hour controls for individuals who are performing the duties of an armed security force officer, alarm station operator, response team leader, or watchperson at a nuclear power plant. Individuals who perform these duties are the members of licensees' security forces who are responsible for implementing the licensees' physical security plans. In order to ensure that these individuals are able to meet their responsibilities for maintaining the common defense and security, it is necessary to ensure that they are not subject to fatigue, which could reduce their alertness and ability to perform the critical job duties of identifying and promptly responding to plant security threats. Security personnel are the only individuals at nuclear power plants who are entrusted with the authority to apply deadly force. Decisions regarding the use of deadly force are not amenable to many of the work controls (e.g., peer checks, independent verification, post-maintenance testing) that are implemented for other personnel actions at a nuclear plant to ensure correct and reliable performance. By contrast to most other nuclear power plant job duty groups, security personnel are typically deployed in a configuration such that some have very infrequent contact with other members of the security force, or other plant personnel. A lack of social contact can exacerbate the effects of fatigue on individuals' abilities to remain alert (Horne, 1988). In addition, these deployment positions can be fixed posts where very little physical activity is required, further promoting an atmosphere in which fatigue could transition into sleep. Many security duties are largely dependent on maintaining vigilance, whereas vigilance tasks are

among the most susceptible to degradation from fatigue (Rosekind, 1997; Monk and Carrier, 2003). Finally, unlike operators, security forces lack automated backup systems that can prevent or mitigate the consequences of an error caused by fatigue. For these reasons, and in light of the excessive hours that some security force personnel were required to work following the elevated threat condition(s) in effect since the terrorist attacks of September 11, 2001, the Commission issued Orders for Compensatory Measures Related to Fitness-for-Duty Enhancements Applicable to Nuclear Facility Security Force Personnel on April 23, 2003. The security force personnel who are subject to work hour controls in the Orders would be the same individuals who would be subject to the proposed work hour controls in this section.

Proposed §26.199(b) [Calculating work hours] would be added to specify the time periods that licensees would include when calculating the work hours of the individuals listed in proposed §26.199(a) for the purposes of this subpart. The NRC's Policy on Worker Fatigue established guidelines for the control of work hours but did not define the concept of "work hours" or establish criteria for calculating them. As a consequence, licensees have inconsistently defined and calculated work hours when implementing the Policy through their technical specifications and administrative procedures. This inconsistency has contributed to some licensees permitting individuals to work excessive hours that caused them to become fatigued. Therefore, the proposed rule would define work hours and requirements for calculating them to ensure consistent implementation of the work hour controls established in this proposed section.

Proposed §26.199(b)(1) [Individual work hours] would be added to specify those portions of a shift that a licensee must include in work hour calculations. The proposed rule would define "work hours" as the amount of time that an individual performs any duties for a licensee who is subject to this section, including all within-shift break times and rest periods

during which there are no reasonable opportunities or accommodations appropriate for restorative sleep, but excluding shift turnover.

The proposed rule specifically would not limit the definition of work hours to hours that are assigned to an individual by the licensee, that are worked on site, or that are worked as part of a scheduled shift, but rather would require licensees to include hours during which an individual performs any duties for the licensee. The proposed rule defines work hours in this broad manner because the NRC is aware that some licensees permit individuals to perform duties on behalf of the licensee from off-site locations and during periods when the individual is not assigned to a shift or scheduled by the licensee to be working on site. For example, because of the large amount of administrative work that is frequently assigned to individuals in the shift manager role, some shift managers stay at work to review and act upon administrative matters after the end of their scheduled shifts in order to complete the reviews and meet deadlines. Anecdotal reports from these individuals have indicated that they may work for 3–4 hours after going off shift to manage their workload, with the result that the hours they have available for personal obligations and, often, sleep are reduced. If the proposed rule limited the calculation of work hours to only those hours that an individual is paid by the licensee, works on shift, and/or is scheduled to be working by the licensee, many individuals may continue to be permitted to work excessive hours and thereby become fatigued. Therefore, proposed §26.199(b)(1) would require licensees to include these work hours in their work hour calculations.

The proposed rule would not require licensees to include the time periods during which an individual participates in shift turnover in the calculation of the individual's work hours. Proposed §26.199(b)(1)(i) would be added to define the specific shift turnover activities that licensees may exclude from their work hour calculations. The proposed rule would define shift

turnover as only those activities that are necessary to safely transfer information and responsibilities between two or more individuals between shifts. Shift turnover is a vital activity, but it also contributes to the length of the work day, and therefore, to worker fatigue. The NRC understands that shift turnovers routinely add approximately 30 minutes to the length of a shift and typically no more than 2–2.5 hours to the length of a typical work week. Stakeholder comments during the public meetings described in Section V highlighted the importance of this activity for communicating plant status information between work crews as well as concern that including turnover time in work hour calculations could cause indirect pressure on individuals to abbreviate shift turnovers in order to ensure that work hour limits would not be violated. This pressure could compromise the quality of shift turnovers and have unintended adverse safety consequences, such as omitting important equipment or maintenance status information. Although some stakeholders believe that turnover is part of the workday and, therefore, should be included in the calculation of hours worked, the NRC believes that the benefit of including turnover for managing worker fatigue would be outweighed by the potential adverse consequence on the quality of shift turnovers.

The proposed exclusion of shift turnover from the work hour calculations would be consistent with the current requirements in most licensee technical specifications for the control of work hours for personnel performing safety-related functions, and with GL 82-12. For example, most technical specifications state, "An individual should not be permitted to work more than 16 hours in any 24-hour period, nor more than 24 hours in any 48-hour period, nor more than 72 hours in any 7-day period, all excluding shift turnover time;" (see SECY-01-0113, Fatigue of Workers at Nuclear Power Plants, Attachment 1, Table 2). However, the proposed rule would more clearly describe the activities may be included in turnover and the activities that may not be included. The proposed provision would address NRC concerns arising from

observations that licensees have occasionally excluded 2 or more hours from calculated work hours on the basis that the individuals were engaged in “turnover.” In order to ensure that turnover is not hurried, the proposed rule would not establish a time limit for an acceptable turnover period. However, by clearly delineating the activities that licensees may consider to be turnover activities, the proposed rule would reduce the potential for individuals and/or licensees to use the proposed shift turnover exclusion to perform other work activities.

Proposed §26.199(b)(1)(ii) would be added to permit licensees to exclude within-shift breaks and rest periods from their work hour calculations only if the individual has both a reasonable opportunity and accommodations for restorative sleep. The proposed rule would permit licensees to exclude breaks from the accounting of work hours only when the exclusion can be justified on the basis that the break substantively mitigates fatigue. The proposed exclusion would be added to address circumstances in which workers may be scheduled for round-the-clock duties (e.g., dedicated fire brigades) during which they are on site and available to respond as needed, but the licensee provides sleeping accommodations and the individuals are allowed periods of time to obtain restorative sleep. This proposed exclusion would also permit licensees to make use of strategic napping, a well-proven fatigue countermeasure (McCallum, et al., 2003; Petrie, et al., 2004; Rosekind, et al., 1994, 1995; Dinges, et al., 1988; Kemper, 2001; Schweitzer, et al., 1992; Sallinen, et al., 1998), without requiring the nap period to be included in work hour calculations.

The proposed exclusion would be limited to that portion of a break or rest period in which there is reasonable opportunity for restorative sleep. For example, a 15-minute coffee break would not provide a reasonable opportunity for restorative sleep. The proposed requirement would be worded to limit the exclusion to the amount of the time the individual has available to actually sleep, and would not include transit time to and from the sleep

accommodations. The term, “restorative sleep,” means an amount of sleep that mitigates fatigue, which is generally considered to be a minimum of approximately 30 minutes (Buxton, et al., 2002; McCallum, et al., 2003; Sallinen, 1998; Rosekind, 1995).

The proposed provision would also require that individuals must have available reasonable accommodations for sleep in order to exclude the break period from the calculation of the individual’s work hours. Reasonable accommodations would include a sleep surface in a darkened, quiet room (e.g., bed, recliner) (Priest, 2000).

This degree of specificity in the proposed paragraph would be necessary because presently some licensees exclude within-shift breaks from the calculation of work hours required by their technical specifications. Excluding break periods from the calculation of work hours can add up to as many as 12 hours over the course of a week, which permits individuals to work an additional 12-hour shift. As a consequence, licensees may assign seven consecutive 12-hour shifts to individuals, but only include 72 hours in their work hour calculations, rather than the 84 hours that the individuals are actually at work. This practice permits individuals to work continuous 12-hour shifts without the licensee having to authorize a deviation from technical specification requirements. The discussion of proposed §26.199(d)(1)(iii) details the basis for limiting individuals to 72 work hours per week.

Although breaks without sleep have some fatigue mitigation value (Tucker, Folkard and Macdonald, 2003), the benefits are principally limited to short-term improvements in vigilance. Horne (1988), Mitler and Miller (1996), and Dinges, et al. (1997) have pointed out that the only non-pharmacological cure for fatigue is sleep. The duration of within-shift break times is normally insufficient to allow a worker to obtain sleep and, consequently, these periods add to the total amount of time an individual remains awake while at work. Time since awakening is a principal determinant of worker fatigue (Folkard and Akerstedt, 1992; NTSB, 1994; Akerstedt,

2004) and performance generally declines as a function of the amount of time that an individual remains awake (Dawson and Reid, 1997). Because within-shift breaks and rest periods provide only short-term mitigation of fatigue (Kruger, 2002; Baker, et al., 1990), the proposed rule would require licensees to include short breaks in the calculation of work hours.

Proposed §26.199(b)(1)(iii) would be added to permit licensees to assign individuals, who are qualified to perform the duties listed in proposed §26.199(a), to other duties than those listed in proposed §26.199(a), without controlling their work hours in accordance with the work hour controls contained in proposed §26.199(d). However, if these individuals would be assigned or returned to performing any duties that are listed in proposed §26.199(a) during the averaging period, the proposed paragraph would require the licensee to include all of the hours that they worked when calculating the individuals' work hours for the averaging period and to subject the individuals to the work hour controls in proposed §26.199(d). For example, if a licensed operator was assigned to training for an entire averaging period, then his or her work hours would not be subject to proposed §26.199(d) for that period because he or she would not be performing any of the duties listed in proposed §26.199(a)(1). However, if the same individual was assigned to training for only a portion of the averaging period and performed the duties listed in proposed §26.199(a)(1) during the remainder of the averaging period, all of his or her hours, including those worked while assigned to training, would be included in the calculation of the individual's work hours for the period and would be included in the operations job duty group collective work hours average, as if the individual was performing operations duties for the entire averaging period. Licensees would be required to count the hours that the individual worked performing other duties if an individual begins performing the duties listed in proposed §26.199(a) during the averaging period because the individual's level of fatigue is largely dependent on the total number of hours he or she has worked, regardless of where the

work was performed or the nature of the work itself. Therefore, including the hours worked performing other duties would provide assurance that fatigue would not compromise that individual's ability to safely and competently perform the duties that are specified in proposed §26.199(a).

Proposed §26.199(b)(2) [Collective work hours] would be added to establish requirements for calculating the collective work hours of the job duty groups that would be subject to the collective work hour limits in proposed §26.199(f) [Collective work hour limits]. (The collective work hour limits and the bases for establishing them are discussed with respect to proposed §26.199(f).) Specifically, the proposed rule would require licensees to calculate, at a minimum, a separate work hour average for each job duty group in proposed §26.199(a). (Appropriate methods for defining job duty groups to which the collective work hour limits would be applied are discussed with respect to proposed §26.199(b)(3).)

Proposed §26.199(b)(2) would limit the length of any averaging period that licensees may use for calculating collective work hours to no more than 13 weeks. In proposing to limit the averaging period to no more than 13 weeks, the NRC considered the need to account for periods of elevated work hours, which have the potential to cause fatigue, as well as the need for an averaging period that would not be unduly influenced by short-term variations in work hours. The NRC also considered industry comments during the stakeholder meetings discussed in Section V expressing a desire for an averaging period that is consistent with other surveillance or assessment requirements. The proposed requirement would provide the flexibility for licensees to use a 13-week averaging period that may be aligned with quarterly reviews or shorter periods that coincide with existing time-keeping practices (e.g., a multiple of pay periods). The proposed flexibility to use shorter averaging periods would also accommodate other circumstances, such as an outage period that occurs within a 13-week

averaging period, during which the proposed rule would not require licensees to implement the collective work hour controls, as permitted in proposed §26.199(f)(2)(iii). Licensees may choose to define shorter averaging periods in these circumstances in order to synchronize subsequent averaging periods with their other scheduling demands (e.g., quarterly reviews, pay periods, the calendar or fiscal year).

The NRC considered both shorter and longer periods in determining the proposed maximum duration for an averaging period. The NRC rejected requiring a shorter maximum averaging period because it would increase the potential for short-term (e.g., 2–3 weeks) emergent work conditions to cause group averages to exceed the 48-hour collective work hours limit in proposed §26.199(f), if overtime is required to respond to the emergent work. These short-term work periods of high overtime use have limited potential for causing cumulative fatigue, considering the individual work hour controls in proposed §26.199(d). Therefore, group averages that are based on shorter averaging periods may overestimate the cumulative fatigue of a job duty group. By contrast, increasing the averaging period to more than 13 weeks would permit a job duty group to work for more than three weeks at the individual limit of 72 hours in 7 days in proposed §26.199(d)(1)(iii) without raising the group average above the 48-hour limit. Therefore, repeated periods of elevated group work hours would not be reflected in the job duty group average and may cause a licensee to delay taking any short-term or long-term corrective actions that may be necessary to control cumulative fatigue within a job duty group. Therefore, the NRC determined that the 13-week averaging period would provide the appropriate level of sensitivity for licensees to identify and respond to conditions that present a significant potential for cumulative fatigue.

Proposed §26.199(b)(2)(i) would be added to permit licensees to calculate collective work hours for each of the broad job duty groups that is listed in proposed §26.199(a) or

smaller sub-groups that would be comprised of individuals who are performing similar duties within any of these broad job duty groups. However, the proposed rule would also require that licensees who elect to calculate collective work hours for smaller sub-groups must ensure that the work hours of all individuals in the broader job duty groups listed in proposed §26.199(a) are included in the collective work hour calculations of a smaller job duty group. That is, the proposed rule would require licensees to ensure that the work hours of all individuals who perform job duties that require them to be subject to the proposed work hour controls of this section are counted. The proposed rule would not permit licensees to combine the broad job duty groups into a larger group (e.g., combining the operations and maintenance groups) because doing so may mask excessive work hours in one of the job duty groups. Separate calculations for each job duty group would be necessary to ensure that the work hours of each job duty group as a whole would be maintained at a level that is consistent with the proper management of cumulative fatigue.

In establishing the requirements for calculating collective averages in proposed §26.199(b)(2)(i) (i.e., determining how many job functions may be included in a collective average), the NRC weighed the merits of limiting the job duty groups to narrow collections of similarly qualified individuals who are capable of performing each other's duties, and therefore sharing workload and work hours. Requiring licensees to calculate collective work hours for smaller sub-groups would provide a more precise indication of work hours. Defining smaller sub-groups would also provide greater assurance of identifying groups of individuals who may be working excessive hours because of inadequate staffing for specific job skills.

However, the proposed rule would not require licensees to calculate collective work hours for smaller sub-groups for several practical reasons:

(1) It would be difficult to define such groups in the rule in a manner that licensees could interpret and implement consistently, considering the diversity of their organizational structures and nomenclature for job duties;

(2) Individuals within the broad job duty groups may be qualified to perform functions in multiple sub-groups. Therefore, assigning these individuals to an appropriate sub-group would be challenging and likely to result in inconsistent implementation of the proposed rule; and

(3) Individuals would be likely to transition between sub-groups within an averaging period due to changes in their work focus or qualifications, which would impose a significant burden on licensees to track each individual's sub-group membership.

For these reasons, the proposed rule would not require licensees to define narrower sub-groups, although it would permit licensees to define such sub-groups for calculating collective work hours.

The proposed requirements for defining groups for calculating collective work hours would ensure that, at a minimum, collective work hour calculations would provide an indication of a licensee's control of work hours for broad licensee functions (e.g., operations, maintenance, security) that are important to the protection of public health and safety and the common defense and security. Further, proposed §26.199(j)(2) and (4) would require licensees to identify and take corrective action for instances of excessive work hours indicating inadequate staffing for any job that would be subject to the work hour controls of proposed §26.199(f). Therefore, collective work hour calculations for broad job duty groups would appropriately support the objectives of the collective work hour controls, when implemented in conjunction with the requirements of proposed §26.199(j)(2) and (4), and provide assurance that the work hours of each job duty group as a whole would be maintained at a level that is consistent with the proper management of cumulative fatigue.

Proposed §26.199(b)(2)(ii) would be added to require licensees to include, in the calculation of collective work hours for each job duty group, the work hours of any individual who performs the job duties of the job duty group, as determined by the licensee in accordance with proposed §26.199(b)(2)(i). The NRC intends the term, “any individual who performs,” as used in proposed §26.199(b)(2)(ii), to mean individuals who are qualified to perform the specified duties.

The NRC considered limiting the calculation of collective work hours to individuals who actually performed the duties of the job duty group during the averaging period. However, during the stakeholder meetings discussed in Section V, industry representatives indicated that this alternative would result in a substantial administrative burden associated with tracking whether each individual actually performed any duties of the group during the averaging period. The NRC considered this comment, as well as the increased volatility of group size and membership that would result from the alternative approach, and concluded that the administrative simplification of defining group membership based on qualifications would substantially reduce the burden of the proposed requirement without a commensurate reduction in the effectiveness of the collective work hour controls in addressing cumulative fatigue. The proposed approach that is based on qualifications would require licensees to expend significantly fewer resources than tracking which individuals are performing specific tasks on a constantly changing basis. The effectiveness of the work hour controls would not be reduced because the number of individuals who are qualified to perform most of these job duties is not substantially greater than the size of each job duty group. Therefore, the effect of including the work hours of a few individuals who are qualified to perform the groups’ job duties but did not actually perform any of those duties during an averaging period would be minimal.

Proposed §26.199(b)(2)(ii) would also require the licensee to include in the calculations the work hours of “any individual” who performs the specified job duties, regardless of the individual’s employer. The NRC recognizes that many of the job functions in the job duty groups listed in proposed §26.199(a) are performed by C/Vs, as well as by direct employees of the licensee. It is important to provide reasonable assurance that fatigue does not impair the job performance of any individual who performs these duties, irrespective of the individual’s organizational affiliation. Therefore, the proposed rule would require licensees to include in the collective work hours calculations for the appropriate job duty group any work hours of C/V personnel who perform the specified job duties.

Proposed §26.199(b)(2)(ii) would require licensees to include in their calculations only the hours that individuals worked “at the licensee’s site” during the averaging period, but not any hours that the individuals may have worked at other facilities. Therefore, collective work hour calculations would not include any work hours that an individual may have worked during the averaging period, for example, at another nuclear plant, at a non-nuclear power plant, or in any other place or form of employment. The NRC acknowledges that hours worked, irrespective of whether the work is performed at a nuclear power plant or any other place of employment, can contribute to worker fatigue, and that consideration of all hours worked would provide a more complete basis for assessing the potential for worker fatigue. However, in establishing the requirement to include only hours worked at the licensee’s site in the collective work hours calculations, the NRC also considered the practical constraints on the ability of licensees to obtain complete and reliable work hours information from other employers. In addition, the NRC anticipates that licensees would comply with the collective work hour controls of proposed §26.199(f) [Collective work hour limits] by continuing to distribute work hours and rest days among individuals in accordance with the capabilities and needs of the individuals,

consistent with most licensees' current practices. Accordingly, the proposed work hour requirements would apply only to those work hours which the licensee can directly control and manage, which are the hours that an individual works for the licensee.

A second implication of adding the phrase, "at the licensee's site," to the proposed paragraph is that the proposed rule would prohibit licensees from combining all of the individuals across a fleet of plants who may be subject to the same FFD program into one of the broad job duty groups listed in proposed §26.199(a). For example, if one licensee operates units at four different sites, proposed §26.199(b)(2)(ii) would permit the licensee to create an operations job duty group for multiple units at one site, but would prohibit the licensee from combining the work hours of all operations personnel across the four different sites to calculate a fleet-wide group average. The proposed prohibition would be necessary to ensure that the size of the job duty groups is not so large that excessive work hours in a job duty group at one site would be masked by lower work hours in the same job duty group at another site, with the result that the group average would be insensitive to local variations in work hours.

Proposed §26.199(b)(2)(ii) would also require licensees to include in their collective work hours calculations only the work hours of individuals who worked at least 75 percent of the normally scheduled hours of the job duty group. This proposed limitation would ensure that job duty group averages are not artificially suppressed by including the work hours of individuals who worked part-time or substantially less than full-time during the averaging period. For example, the proposed rule would prohibit licensees from including in their calculations the work hours of individuals who were on disability or maternity leave for more than 25 percent of the averaging period, or entered or left the job duty group as a result of a personnel action, without working 75 percent of the group's normally scheduled hours. The proposed limitation would be

necessary to ensure that the collective average would actually represent the work hours of the individuals who comprised the job duty group for the majority of the averaging period.

Proposed §26.199(b)(2)(iii) would be added to require that the licensee-defined averaging periods must comprise consecutive days or days that are separated only by days that licensees would be permitted to exclude from the collective work hour calculations in proposed §26.199(f)(1)–(f)(3) and (f)(5), (h), and (i). That is, the proposed rule would require that the averaging period must comprise consecutive days unless outages, increased threat conditions, plant emergencies, and the other conditions that are specified in proposed §26.199(f)(1)–(f)(3) and (f)(5), (h), and (i) occur during the averaging period. This proposed requirement would be necessary to prevent licensees from selectively constituting averaging periods to meet the collective work hour limits by combining work hours during disparate time periods.

However, if any of the conditions arise that are specified in proposed §26.199(f)(1)–(f)(3) and (f)(5), (h), and (i) (e.g., outages, increased threat conditions, plant emergencies) during an averaging period, the proposed paragraph would permit licensees to combine consecutive days immediately preceding and following the excluded period(s) to constitute a complete averaging period. For example, if the length of a licensee's averaging period is 13 weeks and two weeks of an averaging period had elapsed before an increased threat condition occurred (or an outage period began), the licensee could define an averaging period as including those two weeks and the 11 weeks that followed the end of the increased threat condition.

The objective of proposed §26.199(b)(2)(iii) would be to ensure that collective work hour calculations are representative of typical work hours during a distinct period, to the extent practicable, while recognizing that there may be intervening periods that would be excluded from the collective work hour controls that would disrupt the licensee's normal averaging period

schedule. The proposed rule would permit licensees flexibility in comprising their averaging periods in these instances in order to minimize a potential administrative burden that could result from averaging periods that, because of the exclusion period, are no longer synchronized with other needs (e.g., pay periods, the fiscal year). Because the exclusion periods would occur infrequently, the NRC anticipates that permitting licensees flexibility in constituting averaging periods around an excluded period would not mask any systemic or programmatic weaknesses in the licensees' work hour controls over the long-term.

Proposed §26.199(b)(2)(iv) would be added to require licensees to include in an averaging period all days that are not excluded from the collective work hour controls under proposed §26.199(f))(1)–(f)(3) and (f)(5), (h), and (i). Proposed §26.199(b)(2) would provide licensees substantial flexibility in comprising averaging periods that include, or are contiguous with, periods that would be excluded from the collective work hour controls. However, the proposed rule would add this proposed provision to ensure that licensees' collective work hour calculations are complete and represent the typical work hours of individuals by requiring that all days not specifically excluded from collective work hour requirements would be included in at least one averaging period.

Proposed §26.199(b)(2)(v) would be added to prohibit licensees from including any individual's work hours in more than one averaging period. The proposed rule would prohibit double-counting of work hours to ensure that each collective work hours average would represent the work hours of each job duty group during a discrete period of time.

Proposed §26.199(c) [Work hours scheduling] would be added to require licensees to schedule the work hours of individuals who are subject to this proposed section in a manner that is consistent with the objective of preventing impairment from fatigue due to the duration, frequency, or sequencing of successive shifts. The maximum work hour and minimum break

requirements that are specified in proposed §26.199(d) [Work hour controls for individuals] would be intended for infrequent, temporary circumstances, and not as guidelines or limits for routine work scheduling. In addition, the work hour controls in proposed §26.199(d) would not address several elements of routine schedules that can significantly affect worker fatigue, such as shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation. Therefore, proposed §26.199(c) would require licensees to schedule personnel consistent with preventing impairment from fatigue from these scheduling factors.

The proposed rule would require licensees to address scheduling factors because human alertness and the propensity to sleep vary markedly through the course of a 24-hour period. These variations are referred to as circadian rhythms and are the result of changes in physiology brought about by a circadian clock or oscillator inside the human brain that is outside the control of the individual. Work may be scheduled, and the consequent timing of periods of sleep and wakefulness, in a manner that either facilitates an individual's adaptation to the work schedule or challenges the individual's ability to get adequate rest. Therefore, the duration, frequency, and sequencing of shifts, particularly for personnel who work rotating shifts, are critical elements of fatigue management. The effect of circadian rhythms on worker fatigue is also discussed in Section IV. D. The importance of these elements for fatigue management is reflected in guidelines for work scheduling, such as NUREG/CR-4248 and EPRI NP-6748 (Baker, et al., 1990), and in technical reports, such as the Office of Technology Assessment's report, Biological Rhythms: Implications for the Worker (Liskowsky, 1991). The EPRI report, for example, addresses issues related to the sequencing of day, evening, and night shifts, and the use of break periods between shifts to optimize the ability of personnel to obtain adequate sleep and effectively transition from one shift to another. Although research

provides clear evidence of the importance of these factors in developing schedules that support effective fatigue management, the NRC also recognizes that the complexity of effectively addressing and integrating each of these factors in work scheduling decisions precludes a prescriptive requirement. Therefore, proposed §26.199(c) would establish a non-prescriptive, performance-based requirement.

Proposed §26.199(d) [Work hour controls for individuals] would be added to specify that licensees must establish work hour controls for each individual who performs the duties listed in proposed §26.199(a). The proposed rule would require licensees to establish controls that would limit work periods and provide for breaks that are of sufficient length to allow the individual to obtain restorative rest.

Proposed §26.199(d)(1) would be added to establish work hour limits for consecutive, rolling periods of 24 and 48 hours and seven days. The majority of licensees have incorporated the work hour controls from the NRC's Policy on Worker Fatigue, as disseminated by GL 82-12, into either their technical specifications or administrative procedures. The Policy (including the bases for the individual requirements) has been in place for over 20 years and was the subject of a substantive review that is documented in Attachment 1 to SECY-01-0113. The work hour limits from GL 82-12 also were the subject of substantial stakeholder comment during the public meetings described in Section V. In developing the proposed requirements in this paragraph, the NRC staff considered the information gained through these stakeholder interactions.

Proposed §26.199(d)(1)(i) would limit the number of hours that an individual may work in any 24-hour period. The proposed paragraph would permit individuals to work no more than 16 work hours in any 24-hour period. This proposed limit would be identical to that specified in GL 82-12. Attachment 1 to SECY-01-0113 provides the basis for this proposed limit, which is summarized as follows: Studies have shown that task performance declines after 12 hours on

a task (Folkard, 1997; Dawson and Reid, 1997; Rosa, 1991). Other studies have shown that the relative risk of having an accident increases dramatically after 9 consecutive hours on the job (Hanecke, et al.,1998; Colquhoun, et al.,1996; U.S. DOT, 49 CFR Parts 350, et al., Proposed Rule, May 2, 2000, 65 FR 25544). Further, a maximum of 12 work hours per day was the limit recommended by nine experts who met in 1984 to develop recommendations for NUREG/CR-4248. Therefore, in originally developing the NRC's Policy on Worker Fatigue, the NRC had planned a 12-hour maximum limit, but revised it to 16 hours in response to practical concerns from industry that the 12-hour limit required personnel who worked 8-hour shifts to split shifts when they work overtime. Those practical concerns remain valid, and the proposed rule would retain a 16-hour limit.

Although the proposed rule would permit 16-hour shifts, other work hour limits in the proposed rule would effectively limit the number of 16-hour shifts that licensees could assign. This issue is discussed in greater detail in Section V, with respect to a comment on proposed Subpart I by PROS.

Proposed §26.199(d)(1)(ii) would limit the number of hours that an individual may work in any 48-hour period. The proposed paragraph would permit an individual to work no more than 26 work hours in a 48-hour period, by contrast to the related limit in GL 82-12, which limits individuals' work hours to 24 work hours in any 48-hour period. This proposed change would be made to accommodate the fact that most licensee sites are now working routine 12-hour shifts, rather than routine 8-hour shifts, as was the case when GL 82-12 was published. At that time, the basis for the 24-hour limit was to permit a worker to work one 16-hour double shift, followed by an 8-hour break, and then start another 8-hour shift at the worker's normal starting time, but only in very unusual circumstances. With most plants now routinely working 12-hour shifts, the proposed rule would increase the maximum work hours in a 48-hour period from 24

to 26 hours to decrease the burden on licensees that would be imposed by accommodating situations in which a worker's relief is delayed, or similar circumstances. For example, a 12-hour shift worker could work up to 14 hours in one day and still return to work at his or her normal time the next day, but could only work 12 hours that day. In the extreme, the proposed 26-hour limit would permit an individual to work up to 16 hours one day, followed by a minimum 10-hour break, as required in proposed §26.199(d)(2)(i). The individual would then be limited by the proposed requirement to 10 hours of work over the next 22 hours.

In developing the proposed relaxation of the previous 24-hour limit on the number of hours that individuals can work in 48 hours, the NRC considered several factors. These factors include:

(1) The burden associated with granting a waiver for the additional two hours;

(2) The increased stringency of the criteria for granting a waiver of the work hour limits in proposed §26.199(d)(3) relative to those in plant technical specifications; and

(3) The increased potential for worker fatigue and fatigue-related errors that may accrue from working 26 hours in a 48-hour period versus working 24 hours in that same period.

The increase of two additional work hours during a 48-hour period would likely contribute to some increase in fatigue and fatigue-related errors, particularly when these hours come at the end of a work period of 12 or more hours or coincide with a decrease in an individual's circadian level of alertness, as might be expected at the end of a 12-hour day shift. However, because the revised criteria for granting a waiver of the work hour limits in proposed §26.199(d)(3) are expected to substantially reduce the number of waivers that would be granted, the licensee would have to either delay or turn over any work that the individual is performing when it is necessary for him or her to go off-shift. Either delaying or turning over work could contribute to errors. In addition, licensee use of waivers to exceed the 24-hours of

work in any 48-hour period limit for short durations is common practice. As a result, the NRC believes that the proposed relaxation would principally reduce the paperwork burden, rather than result in an increase in the hours that individuals would actually work under the proposed rule. Accordingly, the proposed relaxation would provide a substantive reduction in burden with a limited net effect on human performance reliability.

Proposed §26.199(d)(1)(iii) would be added to limit the number of hours an individual may work in any 7-day period. The proposed paragraph would limit an individual to working no more than 72 hours in any 7-day period. This proposed limit would be identical to the related limit specified in GL 82-12. Attachment 1 to SECY-01-0113 provides the basis for the proposed limit, which is summarized in this paragraph: In the absence of the break requirements in proposed §26.199(d)(2), the proposed limit could potentially permit a worker to work six 12-hour shifts per week continuously. Studies have shown that longer work schedules cause fatigue (Colquhoun, 1996; Rosa, 1995). Human reliability analysis experts have recommended that the NRC set "a maximum of 60 hours in any 7-day period and a maximum of 100 hours in any 14-day period," noting studies indicating that fatigue from long work hours can result in personnel developing their own subjective standards of what is important in their jobs (NUREG/CR-1278, “Handbook on Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications”). Further, NUREG/CR-4248 recommends a limit of 60 hours of work in a 7-day period. However, in the NRC’s Policy on Worker Fatigue, the NRC established a 72-hour maximum limit based on the expectation that individuals would work up to this limit on an infrequent and temporary basis. The proposed rule would codify this expectation, in part, through proposed §26.199(d)(2)(iii), which would require licensees to schedule a 48-hour break every 14 days for individuals who are subject to the proposed work hour controls, and would, thereby, effectively prevent an individual from working six 12-hour shifts for more than 1 week at a time.

Proposed §26.199(d)(2) would be added to require licensees to provide adequate rest breaks for individuals who are performing the duties listed in proposed §26.199(a). This proposed requirement would be necessary to ensure that licensees provide individuals with sufficient time off between work periods (shifts) to permit the individuals to recuperate from fatigue and provide reasonable assurance that acute and cumulative fatigue do not compromise the abilities of these individuals to safely and competently perform their duties. Acute fatigue results from excessive cognitive work, especially if an individual is missing significant amounts of sleep, and is readily relieved by obtaining adequate rest and sleep. Cumulative fatigue results from receiving inadequate amounts or poor quality sleep for successive days. An extensive body of research has shown that a lack of adequate days off and extended workdays result in a cumulative sleep debt and performance impairment [Williamson and Feyer, 2000; Tucker, 1999; Colquhoun, 1996; Baker, et al., 1994; Webb and Agnew,1974; U.S. DOT (65 FR 25546; May 2, 2000)].

Proposed §26.199(d)(2) would define a rest break as an interval of time that falls between successive work periods, during which the individual does not perform any duties for the licensee. For example, during rest breaks, individuals would not be performing work-related duties such as completing paperwork reviews, mandatory reading, or required self-study. Rest breaks could include periods during which an individual is “on-call” because actual demands on an individual’s time while he or she is on-call would be infrequent and of limited duration, such as answering a phone call. However, if an individual who is “on-call” is “called-in” to report to the site, the licensee would be required to include the hours that the individual worked as work hours, rather than as break time, because the individual would be performing duties on behalf of the licensee while on site. The proposed rule would permit individuals to conduct shift turnovers within rest break periods, as discussed with respect to proposed §26.199(b)(1)(i).

Proposed §26.199(d)(2)(i) would be added to require licensees to provide a 10-hour break between successive work periods, but would permit 8-hour breaks in limited circumstances in which a shorter break would be necessary for a crew's scheduled transition between work schedules. Current licensee technical specifications and administrative procedures that are based on GL 82-12 require a minimum 8-hour break between work periods. Proposed §26.199(d)(2)(i) would increase the minimum break period from 8 hours to 10 hours in order to provide greater assurance that individuals have an adequate opportunity to obtain the 7-8 hours of sleep that are recommended by most experts in work scheduling and fatigue. When considering shift turnover and commute times, which do not provide individuals with opportunities for rest and recovery, a nominal rest break of 8 hours actually leaves the individual with approximately 6 hours available to meet personal needs, including sleep (8.0 hours off-duty minus an average 1.5-hour round-trip commute minus an average 0.5 hours spent in shift turnover, equaling 6 hours available for personal needs). However, individuals typically also require 0.5 hours for preparing (or buying) and eating at least one meal off-shift, and 0.5 hours for personal hygiene, which leaves, at best (i.e., assuming no social or domestic commitments that day), a total of 5 hours available for sleep. By contrast, the 10-hour break would ensure that individuals would generally have 7 hours available each day for sleep, which is close to the 7-8 hours of sleep needed by adults in the U.S. (National Sleep Foundation, 2001; Monk, et al., 2000; Rosekind, et al., 1997; Rosa, 1995).

The scientific literature provides strong evidence of the negative effects on performance and alertness of a week of sleep restriction to 5 hours. Dinges, et al., 1997, and Belenky, et al., 2003, who both represent key laboratories in the field of sleep deprivation (the University of Pennsylvania and the Walter Reed Army Institute of Research, respectively), have conducted studies in this area. Belenky, et al. (2003) clearly demonstrates that limiting sleep to 5 hours

per night leads to significant impairment in both alertness and actual performance, which builds up over the week, compared to the alertness and performance of individuals who obtain 7 hours of sleep per night. The difference was found to be significant on all days during which sleep was restricted to 5 hours. Compared to the research subjects' performance after two baseline nights during which they obtained 7 hours of sleep, the subjects' performance after nights during which they were restricted to 5 hours of sleep showed more than twice as many lapses (extra slow responses). Dinges, et al. (1997) obtained similar results. From the second baseline day (the last day during which a full 7 hours of sleep was obtained) through the seven partial sleep restriction days, the research subjects' sleepiness and performance became progressively worse and these effects achieved a high level of statistical significance. The Dinges, et al. study also concluded that "...recovery from these deficits appeared to require two full nights of sleep."

The importance of adequate sleep and the need to provide adequate opportunity for sleep in work schedules are reflected in studies (e.g., Kecklund and Akerstedt, 1995; Wylie, et al., 1996), guidelines (Pratt, 2003; Baker, et al., 1990), handbooks (Tepas and Monk, 1987), and the panel recommendations of sleep and fatigue experts (e.g., NUREG/CR-4248). The importance of providing an opportunity for at least 8 hours of sleep is also noted in an EPRI/NEI Work Hours Task Force white paper, Managing Fatigue in the Nuclear Energy Industry: Challenges and Opportunities (ADAMS Accession No. ML0221740179). The report, prepared by Mark Rosekind, states that "the strongest and most extensive data demonstrate that sleep is a critical factor in promoting alertness and performance in *subsequent* wakefulness. Data clearly show that acute and cumulative sleep loss degrade subsequent alertness and performance. Therefore, any 'hours of service' policy should emphasize the provision of an appropriate sleep opportunity prior to duty." More specifically, human reliability analysis experts

have recommended that the NRC require ”a break of at least 12 hours between all work periods” (NUREG/CR-1278). Similarly, a panel of sleep and fatigue experts criticized a DOT requirement for an 8-hour break for motor carriers as inadequate because 8 hours of off-duty time does not translate into 8 hours of sleep. The DOT has since amended its regulations for motor carriers to require 10-hour rest breaks (68 FR 22456-22517; April 28, 2003).

Although a longer minimum rest break requirement would provide greater assurance that individuals have adequate opportunities for sleep, the proposed 10-hour break requirement would provide adequate opportunity for rest when used infrequently, as would be expected given other requirements in this proposed rule. For example, proposed §26.199(d)(1)(ii) would limit individuals to working 26 hours in any 48-hour period. Although licensees could use routine 10-hour breaks in conjunction with atypical shift durations (e.g., alternating 12- and 14-hour shifts), the practical implications of these schedules, such as varied start times, make their use improbable. As a consequence, the 10-hour break requirement would be sufficient to assure adequate rest during infrequent circumstances in which individuals may work extended hours (e.g., more hours than their typical 8-,10-, or 12-hour shift) and that rest opportunities would typically vary between 12 and 16 hours in duration.

The proposed minimum 10-hour break duration would also accommodate most scheduling circumstances for the common shift durations that are currently in use in the industry. A notable exception is that the proposed 10-hour break requirement could potentially prevent an individual who has worked 16 hours straight (e.g., two consecutive 8-hour shifts) from returning to duty at the start of his or her next regularly scheduled shift. However, the 10-hour break requirement would appropriately prevent the individual from working in this circumstance, because the potential for degraded job performance resulting from fatigue would be substantial, given the individual’s continuous hours of work and limited opportunity to sleep.

Proposed §26.199(d)(2)(i) would permit a minimum 8-hour break in only one circumstance. That is, the proposed paragraph would permit licensees to schedule an 8-hour break, if the 8-hour break is necessary to accommodate a crew's scheduled transition between work schedules. During the public meetings described in Section V, the NRC received comments that the proposed 10-hour break would occasionally interfere with a transition from 12-hour shifts to 8-hour shifts. This transition would typically occur at the end of an outage for individuals who normally work an 8-hour shift, but work a 12-hour shift during outages. Although the proposed exception would provide individuals with less time for recovery, the shorter break would be limited to one break occurring on a very restricted frequency. Therefore, the proposed permission for an 8-hour break in the circumstances of a shift transition would provide scheduling flexibility with minimal potential to adversely affect an individual's ability to safely and competently perform his or her duties.

Proposed §26.199(d)(2)(ii) would be added to require a 24-hour break in any rolling 7-day period. Break periods longer than 10 hours between shifts are necessary on a regular basis in order to maintain reliable human performance. For example, Belenky, et al. (2003) found that the performance of subjects whose sleep periods were restricted to 7 hours per night over 7 consecutive days increasingly degraded as the number of sleep-restricted days increased. Van Dongen, et al. (2003) similarly found that the performance of subjects whose sleep was limited to 8-hours per night also declined over a two-week period. The only subjects in these studies who did not show any performance decrements were those who were permitted 9-hour sleep periods in the Van Dongen study. These results clearly demonstrate that individuals require more rest than a 10-hour break provides over time to prevent performance degradation from cumulative fatigue, including that which accrues from a series of days of mild sleep restriction (e.g., 7 hours per night).

Further, a 10-hour break provides an opportunity for 7 hours of sleep only if one assumes the minimal times for meals, hygiene, and commuting described with respect to proposed §26.199(d)(i), with no other daily living obligations. These assumptions are realistic only for unusual circumstances and limited periods of time during which individuals may be able to temporarily defer their other obligations. As the number of consecutive days increases on which individuals have only a 10-hour break available to meet these other obligations, the pressure on individuals to restrict sleep time in order to meet these other obligations increases. In addition, after a series of moderately restricted sleep periods (i.e., 6 hours per night), individuals' subjective feelings of sleepiness stabilize and they report feeling only mild sleepiness (Van Dongen, et al., 2003), which may further encourage individuals to restrict their sleep periods in order to meet daily living obligations. Van Dongen, et al. noted "...the lack of reports of intense feelings of sleepiness during chronic sleep restriction may explain why sleep restriction is widely practiced – people have the subjective impression they have adapted to it because they do not feel particularly sleepy." However, results of the Van Dongen study also demonstrated that the performance of subjects in that study continued to degrade as the number of consecutive restricted sleep periods increased over a two-week period, including the performance of subjects who were permitted 6- and 8-hour sleep periods.

Therefore, the proposed provision for a 24-hour break in any rolling 7-day period would serve both to prevent and mitigate cumulative fatigue. The proposed 24-hour break periods would not only provide some opportunity for recovery sleep, but also time that individuals need to meet the many daily living obligations that they cannot otherwise readily meet. Without such long break opportunities, individuals must either forego activities that can be important to general mental and physical fitness (e.g., family interactions, exercise, recreation, doctor

appointments) or sacrifice sleep and increase their sleep debt (Presser, 2000), resulting in impairment on the job.

Significant considerations in the NRC's development of proposed §26.199(d)(2)(ii) and (d)(2)(iii) were industry work scheduling practices during outages and the applicability of other proposed requirements during these periods. In SECY-01-0113 and NRC staff reviews of records of deviations from technical specification work hour controls from 2003 and 2004, the most common deviation identified was to permit individuals to work more than 72 hours in 7 days, frequently by working more than six consecutive 12-hour days. These reviews also indicated that this practice was used extensively at a number of sites. Industry comments at the public meetings described in Section V also confirmed the NRC observation that some licensees were scheduling outages with several weeks of 12-hour shifts with no scheduled days off. This practice would be inconsistent with the findings of the studies and recommendations cited in the discussions of proposed §26.199(d)(1)(iii) and (d)(2)(ii).

Although the NRC expects that the proposed criteria for granting waivers from the individual work hour controls in proposed §26.199(d)(3) would significantly reduce the granting of waivers, the proposed maximum individual work hour requirements of proposed §26.199(d)(1) would not preclude licensees from scheduling consecutive 10-hour shifts with no days off. In addition, although the collective work hour controls in proposed §26.199(f) would limit cumulative fatigue from broad and extended use of such schedules while plants are operating, these controls would not apply during the first 8 weeks of plant outages, and in other circumstances for security personnel, as detailed in proposed §26.199(f)(2). Therefore, the proposed work hour controls of §26.199(d)(1) and (f) would not effectively prevent cumulative fatigue for roving outage crews and other transient workers who predominantly work during plant outages.

By contrast, the long break requirement of proposed §26.199(d)(2)(ii) would provide an important protection against cumulative fatigue for individuals who work consecutive outages, as well as for all individuals who perform the duties listed in proposed §26.199(a) during extended plant outages. One stakeholder observed during one of the public meetings described in Section V that assuring transient outage workers are not impaired by fatigue is particularly important because these individuals typically do not have the extensive training in methods for maintaining reliable human performance that is provided to permanent plant personnel.

Proposed §26.199(d)(2)(iii) would be added to further require licensees to provide individuals with a 48-hour break in any rolling 14-day period. A detailed discussion of the bases for requiring extended breaks is provided with respect to proposed §26.199(d)(2)(ii). In addition to the bases for the 24-hour break requirement, the details of which also apply to this proposed requirement, a 48-hour break every 14 days is further justified because the maximum individual work hour requirements of proposed §26.199(d)(1) and the 24-hour break requirement in proposed §26.199(d)(2)(ii) would not preclude licensees from scheduling a series of weeks that required individuals to work six consecutive 12-hour shifts with only one day off. However, only one day off is insufficient to recover completely from chronic sleep restriction.

The need for at least two consecutive unrestricted sleep periods to recover from restricted sleep and periods of extended work hours has been demonstrated in several studies. Surveys (National Sleep Foundation, 2001, 2002) and studies (Monk, et al., 2001) of actual sleep patterns of shiftworkers show that shiftworkers sleep longer on “weekends” (i.e., periods of two or more days off), indicating a need for recovery sleep that is not being met during the workweek. In the Belenky, et al. (2003) study that was discussed with respect to proposed §26.199(d)(2)(ii), the performance of the sleep-restricted subjects, including those whose sleep

periods were restricted to 7 hours, did not return to baseline levels on all performance measures, even after 3 recovery nights of 8-hour sleep periods. Further, in a personal communication on March 22, 2005 (ADAMS Accession No. ML050870172), Dr. David Dinges stated that he and his colleagues at the sleep lab at University of Pennsylvania Medical School are currently conducting large-scale studies of the recovery process and that preliminary results from these studies appear to confirm the Belenky, et al. findings. He noted that one night of unrestricted sleep is generally insufficient because individuals' circadian rhythms will not permit them to sleep for the 12–14 hours that may be required to recover from a series of days on which sleep has been moderately restricted. In addition, Dr. Dinges reported that a scientific consensus has emerged within the research community that at least two consecutive nights of unrestricted sleep periods are the minimum essential for recovery. Two consecutive nights' are required because, as discussed in Section IV D(2)(c), individuals' circadian rhythms decrease the length of daytime sleep periods and daytime sleep interruptions are common.

The need for longer breaks to mitigate fatigue was also reflected in recent changes to DOT's regulations for the work hours of commercial truck drivers. On April 28, 2003, the DOT published final regulations (68 FR 22456-22517) for hours-of-service for drivers of motor carriers, which amended 49 CFR 385, 390, and 395. These regulations require a minimum 34-hour break after any period of 8 consecutive days with no more than 70 hours on duty. The intent of this 34-hour break is to provide for two consecutive sleep periods. The regulations also limit drivers to 11 hours of driving and 14 hours on duty with 10 consecutive hours off duty each day.

The importance of long breaks is also reflected in work scheduling guidelines such as EPRI NP-6748, "Control Room Operator Alertness and Performance in Nuclear Power Plants." With respect to the number of consecutive shifts, EPRI recommends no more than 6–7

consecutive 8-hour shifts and no more than 3–4 consecutive 12-hour shifts. With respect to the number of consecutive days off, EPRI recommends a break of at least 48 hours between any two blocks of shifts and at least one 3–4 day break every few weeks. Similarly, a panel of independent experts in fatigue and work scheduling, convened by the NRC (NUREG/CR-4248), recommended that work schedules should include no more than 7 consecutive 8-hour shifts and at least 2 consecutive days off in any 9 days and a maximum of 4 consecutive 12-hour shifts followed by no fewer than 4 days off. Proposed §26.199(d)(2)(iii) would establish a minimum break requirement that would be somewhat less stringent than these scheduling guidelines.

In many nations a routine 72-hour work week would be illegal (OTA, 1991). As a consequence, studies of the effects of continuous weeks of working six consecutive 12-hour shifts are sparse. However, there are a few studies concerning the work hours and performance of medical residents who, like many nuclear power plant personnel, perform largely cognitive tasks. By contrast to the majority of individuals working at nuclear power plants, medical residents are typically young adults with few family commitments. This characteristic is important because social and domestic commitments inevitably limit sleep time (Presser, 2000) and there are significant decrements in the abilities of middle-aged men to adapt to the changes in sleep schedules required by shiftwork compared to younger adults (Monk, Moline and Graeber, 1988; Carrier, et al., 1997; Dawson and Campbell, 1991). However, despite lifestyle and age differences between medical residents and nuclear power plant workers, the underlying physiological processes affected by fatigue are the same in both groups. Therefore, research on the effects of cumulative fatigue on the job performance of medical residents is useful in understanding the potential effects of fatigue on nuclear power plant personnel, although generalizing the findings of research conducted with medical

residents to nuclear power plant workers likely underestimates the effects of fatigue on nuclear power plant workers' job performance because of their greater average age.

Two key publications, (Baldwin, et al., 2003; Baldwin and Daugherty, 2004) report survey data from more than 3,600 medical residents. These studies found that almost half of the sample worked more than 80 hours per week. When the residents who worked more than 80 hours per week were compared to those working fewer than 80 hours, it was found that the former group had a statistically higher likelihood of (1) having a serious accident or injury; (2) having a serious conflict with a co-worker; and (3) making a significant medical error. Work hours were also significantly correlated with sleep loss and ratings of stress.

Similarly, two studies were conducted comparing the performance of medical interns on their traditional schedule, which totaled 77–81 hours per week and included on-call shifts that extended up to 30 hours, with the performance of these same interns during an intervention schedule. The intervention schedule averaged approximately 65 hours per week and reduced shift lengths to a maximum of 16 hours. Lockley and colleagues found that interns on the intervention schedule had less than half the rate of attentional failures during on-call night shifts compared with their rate of attentional failures while working on the traditional schedule (Lockley, et al., 2004). In another study, Landrigan and colleagues found that interns on the traditional schedule made 35.9 percent more serious medical errors and 56.5 percent more serious, non-intercepted errors than interns working on the intervention schedule. The rate of serious errors on the critical care unit was 22 percent higher during the traditional schedule. Interns made 20.8 percent more serious medication errors and 5.6 times as many serious diagnostic errors on the traditional schedule (Landrigan, et al., 2004).

These studies suggest that nuclear power plant workers who work long shifts over extended periods are substantially more likely to commit errors on the job. Fatigue from

extended periods of working long shifts is likely to lead to serious errors, impaired teamwork, and an increased potential for personal injuries.

Except during the first 2 weeks of a plant outage, proposed §26.199(d)(2)(iii), in conjunction with the other proposed work hour limits, would require a schedule very similar to the intervention schedule for the medical interns. Specifically, proposed §26.199(d)(2)(iii) would require a 48-hour break in every rolling 14-day period, effectively limiting individuals who perform the job duties listed in proposed §26.199(a)(1)–(a)(4) from working six 12-hour shifts for more than one week at a time. For example, individuals on 12-hour shifts could work six 12-hour shifts during week 1, followed by five 12-hour shifts during week 2. As a result, these individuals would average 66 hours over the two-week period, and would be limited by proposed §26.199(d)(1)(i) to working no more than 16 hours in any 24-hour period.

In addition to being important for permanent workers at nuclear power plants, the 48-hour break requirement would be critical to prevent and mitigate cumulative fatigue in roving outage crews and other transient workers who predominantly work during plant outages when the collective work hour controls in proposed §26.199(f) would not frequently apply. During the stakeholder meetings discussed in Section V, many stakeholders expressed a strong desire for transient workers to be subject to work hour controls. The NRC staff considered subjecting transient workers to long-term work hour controls. However, collective work hour controls and 48-hour average group limits would not be practical, because these individuals typically work during outages when significant workloads occur. The NRC staff further considered individual long-term (quarterly and yearly) work hour limits for transient workers. However, industry representatives strongly objected because these transient individuals move from one licensee to another, and the burden of obtaining work hour information for all of these individuals from other licensees would be extremely high. In part because of the practical difficulties of

controlling long-term work hours for transient individuals, the NRC developed the 48-hour break requirement as a replacement for long-term work hour limits for transient individuals.

The NRC further considered that some transient personnel include licensee employees and long-term C/Vs. Many of these individuals may move from site-to-site within a fleet during plant outage periods. For large fleets, some individuals may work much of the spring and fall outage seasons under only the individual work hour limits and break requirements in proposed §26.199(d). The proposed 48-hour break requirement would be the single requirement that would prevent such individuals from working 72 hours per week for extended periods. The proposed 48-hour break requirement would also provide necessary breaks for all individuals who perform the duties listed in proposed §26.199(a) during extended plant outages of more than 2 weeks in duration. In this case, the proposed 48-hour break requirement would again be the single requirement that would prevent individuals from working 72 hours per week for the entire first 8 weeks of any plant outage [collective work hour limits would apply after the first 8 weeks of any plant outage, as discussed with respect to proposed §26.199(f)]. Working 72 hours per week for extended periods is inconsistent with the research cited in this section with respect to proposed §26.199(d)(2)(i) and (d)(2)(ii), nor does the NRC believe it is consistent with providing reasonable assurance that individuals are fit to perform their duties. The 48-hour break requirement of proposed §26.199(d)(2)(ii) would provide an important protection against cumulative fatigue for individuals who work consecutive outages and outages that are longer than two weeks.

Proposed §26.199(d)(3) would be added to permit licensees to authorize waivers from the work hour controls for individuals in proposed §26.199(d)(1) and (d)(2) for conditions that meet two criteria, which would be specified in the proposed paragraph. Exceeding the individual work hour limits would be justified for limited circumstances in which compliance with

the work hour controls could have immediate adverse consequences for the protection of public health and safety or the common defense and security. Limited use of waivers also would be consistent with the Commission's position stated in the NRC's Policy on Worker Fatigue. However, as specified in proposed §26.199(d)(3)(ii), the NRC would expect licensees to grant waivers only to address circumstances that the licensee could not have reasonably controlled.

Proposed §26.199(d)(3)(i)(A) would be added to establish one of two criteria in the proposed rule for granting a waiver from the individual work hours controls. Specifically, proposed §26.199(d)(3)(i)(A) would require that an operations shift manager must determine that the waiver is necessary to mitigate or prevent a condition adverse to safety, or a security shift manager must determine that the waiver is necessary to maintain the security of the facility, or a site senior-level manager with requisite signature authority must make either determination.

The NRC's Policy on Worker Fatigue recognized that "very unusual circumstances may arise requiring deviation from the above [work hour] guidelines." In SECY-01-0113, the NRC noted that the frequency of guideline deviations at a substantial proportion of sites appeared to be inconsistent with the intent of the policy. The NRC believes that the authority to grant deviations from the work hour guidelines was abused by some licensees. Proposed §26.199(d)(3)(i)(A) would more clearly articulate the NRC's expectations with respect to exceeding the work hour limits, which are that licensees must limit the granting of waivers from the work hour limits to circumstances in which it is necessary to prevent or mitigate a condition adverse to safety or to maintain the security of the plant. The proposed criterion would limit waivers to conditions that are infrequent while permitting waivers that are necessary for safety or security. For example, proposed §26.199(d)(3)(i)(A) would permit a licensee to grant a waiver from a work hour control on the basis that the waiver is necessary to prevent a condition

adverse to safety, if compliance with the work hour controls would cause the licensee to be in violation of other NRC requirements, such as the minimum on-site staffing requirements in 10 CFR 50.54(m), or would delay the recovery of failed plant equipment that is necessary for maintaining plant safety. Similarly, the NRC would consider it appropriate to grant a waiver from the proposed work hour controls on the basis that it is necessary to prevent a condition adverse to safety, if compliance with the work hour controls would cause a forced reactor shutdown, power reduction, or other similar action, as a result of exceeding a time limit for a technical specification Limiting Condition for Operation (LCO). LCOs require nuclear power plant licensees to take certain actions to maintain the plant in a safe condition under various conditions, including malfunctions of key safety systems.

The criterion for granting waivers in proposed §26.199(d)(3)(i)(A) was the subject of considerable stakeholder comment and discussion during the public meetings described in Section V. Industry representatives stated that the criterion is overly restrictive because it would prohibit the granting of waivers for conditions that could be cost beneficial to the licensee without a substantive decrease in safety. However, as discussed with respect to proposed §26.199(d)(2) and (d)(3), the potential for worker fatigue in conditions that would require a waiver is substantial (Baker, et al., 1994; Dawson and Reid, 1997; Stephens, 1995; Strohl, 1999). Therefore, the NRC does not believe that licensees can reasonably justify the performance of risk-significant functions by individuals who have worked hours in excess of the proposed limits on the basis that granting the waiver would not have an adverse impact on safety or security. The basis for not incorporating industry's comment on this provision is detailed in Section V.

Proposed §26.199(d)(3)(i)(A) would further require that an operations shift manager or a senior-level site manager with requisite signature authority must make the determination that a

waiver is necessary to mitigate or prevent a condition adverse to safety. Similarly, the proposed rule would require that a security shift manager, or a senior-level site manager with requisite signature authority, must make the determination that a waiver is necessary to maintain the security of the facility. Operations shift managers and security shift managers have the requisite knowledge and qualifications to make the respective safety or security determinations, and making such determinations would be consistent with the scope of duties currently performed by individuals in these positions. The NRC considered industry stakeholder comments during the public meetings described in Section V, expressing concern that limiting the authority to approve waivers to operations shift managers and security shift managers could contribute to overburdening individuals in these positions and would prevent distributing the administrative burden of granting a waiver to other qualified individuals. The NRC also considered other stakeholder comments concerning the need to ensure that the determinations are made by individuals who would not be unduly influenced by schedule pressures. The NRC noted that authority to authorize deviations had been delegated by some licensees to organizational levels that appeared to be inconsistent with the guidelines in the NRC's Policy on Worker Fatigue for work hour deviation authorizations, which indicate that deviations from the guidelines should be authorized by the plant manager or plant manager designee. Accordingly, proposed §26.199(d)(3)(i)(A) would permit senior site managers with the signature authority of operations shift supervisors to make the safety determinations that would be required to grant waivers and senior site managers with the signature authority of security shift supervisors to make security determinations required to grant waivers.

Proposed §26.199(d)(3)(i)(B) would be added to establish the second of two proposed criteria for granting a waiver from the individual work hour controls of proposed §26.199(d)(1) and (d)(2). Proposed §26.199(d)(3)(i)(B) would require that a supervisor, who is qualified to

direct the work to be performed by the individual to whom the waiver will be granted and is trained in accordance with the requirements of proposed §§26.29 and 26.197(c), must assess the individual face to face and determine that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted.

These determinations would require knowledge of the specific skills that are necessary to perform the work and the conditions under which the work will be performed in order to assess the potential for fatigue to adversely affect the ability of an individual to safely and competently perform the work. This knowledge is generally limited to individuals who are qualified to direct the work. The training required by proposed §§26.29 and 26.197(c) would provide the knowledge and abilities that would be essential for a supervisor to make valid assessments in this regard. Among other FFD topics, the proposed training would address the contributors to worker fatigue and decreased alertness in the workplace, the potential adverse effects of fatigue on job performance, and the effective use of fatigue countermeasures. Accordingly, the proposed training would be necessary for individuals to perform these assessments.

Proposed §26.199(d)(3)(i)(B) would further require that supervisors must perform the assessment face to face with the individual that he or she is assessing for the waiver. This proposed requirement would ensure that the supervisor who is performing the assessment has the opportunity to observe the individual's appearance and behavior to note indications of fatigue (e.g., decreased facial tone, rubbing of eyes, slowed speech) and interact with the individual to assess the individual's ability to continue to safely and competently perform his or her duties during the period for which the waiver would be granted.

Proposed §26.199(d)(3)(i)(B) would also require that the supervisory assessment must address, at a minimum, the potential for acute and cumulative fatigue, considering the individual's work history for at least the past 14 days and the potential for circadian degradations in alertness and performance, considering the time of day for which the waiver will be granted. The potential for acute fatigue can be practically assessed by estimating the total number of continuous hours the individual will have worked by the end of the work period for which the waiver is being considered. The potential for cumulative fatigue can be practically assessed by reviewing the individual's work schedule during the past 14 days to determine (1) whether the individual had adequate opportunity to obtain sufficient rest, considering the length and sequencing of break periods; (2) whether the available sleep periods occurred during the night or at other times when sleep quality may be degraded; and (3) the potential for transitions between shifts (e.g., from days to nights) to have interfered with the individual's ability to obtain adequate rest. The potential for circadian degradations in alertness and performance can be practically assessed by considering the time of day or night during which the work would be performed, as well as the times of day of the individual's recent shift schedules. Proposed §26.199(d)(3)(i)(B) would in effect require supervisors to address the three work schedule factors (i.e., shift timing, shift duration, and speed of rotation) that are generally considered to be the largest determinants of worker fatigue (Akerstedt, 2004; McCallum, et al., 2003; Mallis, et al., 2002; Folkard and Monk, 1980; Rosa, 1995; Rosa, et al., 1996). In determining the scope of the proposed assessment, the NRC also considered the need for licensees to be able to focus the assessment on information that would be readily available and could be verified.

Proposed §26.199(d)(3)(i)(B) would further require that the supervisory assessment for granting a waiver must address the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions, and whether it would be necessary to establish

controls and conditions under which the individual will be permitted to perform work. This proposed requirement is consistent with the NRC's Policy on Worker Fatigue, which states that "the paramount consideration in such authorizations shall be that significant reductions in the effectiveness of operating personnel would be highly unlikely." However, proposed §26.199(d)(3)(i)(B) would require the supervisor to identify any risk-significant functions that may be compromised by worker fatigue, thereby focusing the assessment on worker activities that have the greatest impact on the protection of the public, considering the types of skills and abilities that are most sensitive to fatigue-related degradations.

Proposed §26.199(d)(3)(i)(B) would also require the supervisor to identify any additional controls and conditions that he or she considers necessary to grant the individual a waiver from a work hour control. For example, applicable controls and conditions may include, but would not be limited to: (1) peer review and approval of assigned job tasks; (2) assignment of job tasks that are non-repetitive in nature; (3) assignment of job tasks that allow the individual to be physically active; and (4) provisions for additional rest breaks. The proposed requirement to consider establishing controls and conditions would be necessary to ensure that licensees take steps to mitigate fatigue from an extended work period and reduce the likelihood of fatigue-related errors adversely affecting public health and safety or the common defense and security.

Proposed §26.199(d)(3)(ii) would be added to require licensees, to the extent practicable, to grant waivers only in circumstances that the licensee could not have reasonably controlled. This proposed requirement would be necessary because conditions meeting the waiver criteria that are specified in proposed §26.199(d)(3)(i) could routinely result from inadequate staffing or work planning. Licensees have authorized deviations from their technical specification limits on work hours for these reasons in the past. However, because of the significant adverse effects of worker fatigue, as detailed in Section IV. D, waivers should be

used infrequently and only when necessary to protect the public. Licensees should take all reasonable care to ensure the use of waivers is minimized. Therefore, proposed §26.199(d)(3)(ii) would prohibit the use of waivers in lieu of adequate staffing or proper work planning, for example, but would permit the use of waivers for circumstances that the licensee could not have reasonably controlled, which may include, but would not be limited to, equipment failures or a sudden increase in the personnel attrition rate.

Proposed §26.199(d)(3)(iii) would be added to require that the face-to-face supervisory assessment required in proposed §26.199(d)(3)(i)(B) must be performed sufficiently close in time to the period during which the individual will be performing work under the waiver to ensure that the assessment would provide a valid assessment of the potential for worker fatigue during the extended work period. This proposed requirement would be necessary because worker alertness and the ability to perform can change markedly over several hours (Baker, et al., 1990; Dawson and Reid, 1997; Frobert, 1997; Folkard and Monk, 1980; Rosa, 1995). These changes can be particularly dramatic if fatigue from sustained wakefulness coincides with circadian periods of decreased alertness (Baker, et al., 1990; Gander, et al., 1998; Rosekind, 1997; Folkard and Tucker, 2003; Carrier and Monk, 2000). Therefore, the proposed rule would require licensees to conduct supervisory assessments within a time period that provides reasonable assurance that the individual's condition will not substantively change before work is performed under the waiver.

Proposed §26.199(d)(3)(iii) would establish a period of 4 hours before the individual begins working under the waiver as the period within which the supervisory assessment must be performed. In establishing a maximum time period the NRC considered several factors. Conducting the assessment as close in time as practical to the period during which the individual will perform work under the waiver would provide the greatest assurance of a valid

assessment. However, conducting the assessment immediately before the individual will begin performing work under the waiver could, in some circumstances, cause the timing of assessments to conflict with the conduct of shift turnovers and other practical administrative and operational constraints. Additionally, assessments for granting waivers from the longer-term individual limits (e.g., the maximum number of work hours in 7 days) would be less sensitive to the specific timing of the assessment. However, certain licensees have periodically authorized blanket deviations from technical specification work hour limits days and weeks in advance of the actual performance of the work. A maximum limit of 4 hours would address the need for an enforceable requirement that would provide reasonable assurance of valid assessments, and would take into account the relevant technical and practical considerations. An added benefit of the proposed requirement is that it would prevent the simultaneous granting of blanket waivers for large groups of individuals that do not take into account each individual's level of fatigue.

Proposed §26.199(d)(3)(iv) would be added to require licensees to document the bases for granting waivers from the individual work hour controls of proposed §26.199(d)(1) and (d)(2). The proposed paragraph would require licensees to document the circumstances that necessitate the waiver; a statement of the scope of work and time period for which the waiver is approved; and the bases for the determinations that would be required by proposed §26.199(d)(3)(i). The proposed documentation would be necessary to support NRC inspections of compliance with requirements for granting waivers from the work hour limits as well as for the licensee self-assessments of the effectiveness of implementing work hour controls that would be required under proposed §26.199(j) [Reviews].

Proposed §26.199(e) [Self-declarations during extended work hours] would be added to require licensees to take immediate action in response to a self-declaration [as discussed with

respect to proposed §26.197(b)(1)] by an individual who is working under, or being considered for, a waiver from the work hour controls in proposed §26.199(d)(1) and (d)(2). Licensees would be required to immediately stop the individual from performing any duties listed in proposed §26.199(a) unless the individual is required to continue performing those duties under other requirements of 10 CFR Chapter I, such as the minimum control room staffing requirements in 10 CFR 50.54(m). If other requirements make it necessary for the individual to continue working, the proposed paragraph would require the licensee to immediately take action to relieve the individual. For example, the licensee would immediately begin a call-in procedure for another individual to fill the required position and remove the individual from duties as soon as relief becomes available.

The proposed rule would add this requirement because correct performance of the job duties specified in proposed §26.199(a) is of critical importance in maintaining public health and safety and the common defense and security. In addition, there is a significantly increased potential for fatigue-related errors when individuals work more than the maximum work hours or obtain less rest than the minimum rest requirements of proposed §26.199(d)(1) and (d)(2). Individuals who would be working extended hours under a waiver would have a clear and legitimate basis for a self-declaration of being unfit for duty because of fatigue. Further, by self-declaring fatigue, the individual would have effectively provided an assessment of his or her ability to continue to safely and competently perform these critical duties. Several studies have indicated a tendency for individuals to underestimate their level of fatigue (Wylie, et al., 1996; Dinges, 1995; Rosekind and Schwartz, 1988). Therefore, it is very likely that an individual who would make a self-declaration of fatigue is potentially more impaired than he or she realizes.

The proposed rule would not require licensees immediately to relieve an individual who self-declares when it is necessary for the individual to continue performing his or her duties

under other requirements of 10 CFR Chapter I, because the failure to meet minimum staffing or similar requirements would, in the majority of cases, have a greater potential to adversely affect public health and safety and the common defense and security than permitting a fatigued individual to continue performing his or her duties for a limited period of time. Further, in these circumstances, licensees could implement any fatigue mitigation strategies they deem necessary while the individual remains on duty. Fatigue mitigation measures in these circumstances may include, but would not be limited to, controls on the type of work that the individual may perform until he or she is relieved (e.g., physical or mental, tedious or stimulating, individual or group, risk-significant or not) and an increased level of supervision (continuous or intermittent) and other oversight (e.g., peer checks, independent verifications, quality assurance reviews, and operability checks).

Proposed §26.199(e)(1) would be added to permit licensees to reassign an individual who has made a self-declaration of fatigue to perform other duties than those specified in proposed §26.199(a). The proposed rule would include this flexibility because, although an individual may not be fit to perform the activities specified in proposed §26.199(a), the individual may be able to safely and competently perform other duties. Other duties may include, but would not be limited to, tasks that require skills that are less susceptible to degradation from fatigue or do not have the potential to adversely affect public health and safety or the common defense and security if the individual commits fatigue-related errors. The proposed rule would permit licensees to reassign individuals who have made a self-declaration of fatigue to other duties, if the results of a fatigue assessment (as would be required under proposed §26.201 [Fatigue assessments]) indicate that he or she is fit to perform them, because permitting the individual to remain at work and continue performing such duties would not have the potential to adversely impact public health and safety or the common defense and security.

However, proposed §26.199(e)(2) would be added to require the licensee to permit or require an individual who has made a self-declaration to take a rest break of at least 10 hours before the individual returns to performing any duties listed in proposed §26.199(a). The proposed rule would include this requirement to ensure that individuals who have self-declared would be given an opportunity to sleep before they are permitted to resume performing any duties that have the potential to adversely affect public health and safety or the common defense and security. Sleep is widely considered the only non-pharmacological means of reducing fatigue. As discussed with respect to proposed §26.199(d)(2)(i), a 10-hour rest break generally allows individuals to obtain the 7–8 hours of sleep that is recommended by most experts for maintaining human performance (National Sleep Foundation, 2001; Dinges, et al., 1997; Belenky, et al., 2003; Akerstedt, 2003; Monk, et al., 2000; Rosekind, et al., 1997; Rosa, 1995).

Although one sleep period of 7–8 hours may be insufficient to ensure full recovery from excessive fatigue, nothing in the proposed rule would preclude an individual in this circumstance from making a second self-declaration of fatigue, if the individual believes that he or she remains unable to safely and competently perform his or her duties following the rest break. Section I. B of the May 10, 2002, NRC Regulatory Issue Summary (RIS) 2002-07: "Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declarations of Fitness-for-Duty," addressed the applicability of the protections of 10 CFR 50.7, "Employee Protection," to workers who self-declare that they are unfit for duty as a result of fatigue.

Proposed §26.199(f) [Collective work hour limits] would be added to require licensees to control the collective work hours of each group of individuals who are performing the job duties listed in proposed §26.199(a) and ensure that the collective work hours of each job duty group do not exceed an average of 48 hours per person per week in any averaging period. (The

proposed rule's requirements for calculating collective work hours are discussed with respect to proposed §26.195(b)(2) [Collective work hours].) The requirements of proposed §26.199(f) would address the control of work hours over extended periods of time, by contrast to the short-term work hour controls in proposed §26.199(d) [Work hour controls for individuals].

The objectives of the 48-hour collective limit during normal plant operations would be to: (1) ensure that the routine work hours of individuals who are performing the duties listed in proposed §26.199(a)(1)–(a)(5) do not adversely affect their abilities to safely and competently perform their duties; (2) define an enforceable upper limit for the nominal 40-hour work-week policy stated in GL 82-12; and (3) continue to permit licensees to manage overtime in a manner that reflects the differing desires and capabilities of individuals with respect to work hours.

The proposed collective work hour controls would ensure that licensees manage the potential for cumulative fatigue (i.e., fatigue from successive weeks or months of overwork or inadequate rest) to adversely affect the abilities of individuals to perform functions that are important to maintaining the safety and security of the plant. The 48-hour collective work hour limit would prevent excessive use of the maximum work hours and minimum rest breaks that would be permitted under the proposed individual work hour controls. In addition, proactively controlling work hours to a group average of no more than 48 hours per week would likely reduce the need for licensees to grant waivers of the individual limits in proposed §26.199(d)(1) and (d)(2). Individuals would be better rested and less susceptible to cumulative fatigue from the increased work hours that are common during outages and are necessary to augment security staffing during increased threat conditions, during which times licensees would not be required to implement group work hour controls, subject to the restrictions listed in proposed §26.199(f)(1)–(f)(5). Therefore, the 48-hour collective work hour limit would be essential for

limiting cumulative fatigue and would augment other important elements of licensees' fatigue management programs.

The collective work hour control concept would be consistent with a fundamental objective of the NRC's Policy on Worker Fatigue. The Policy, promulgated via GL 82-12, is intended to ensure that there are a sufficient number of operating personnel available to "maintain adequate shift coverage without routine heavy use of overtime." Routine overtime can cause cumulative fatigue, thereby degrading workers' abilities to safely and competently perform their tasks. The proposed requirement would, in effect, limit groups of individuals to no more than 20 percent overtime in excess of the nominal 40-hour work week objective of the NRC's Policy on Worker Fatigue during the periods in which the proposed requirement would be applicable (typically during normal plant operations).

The collective work hour controls of proposed §26.199(f) would also codify, in part, the requirements established by Order EA-03-038 for the control of work of hours for specified nuclear power plant security personnel (SRM-COMSECY-03-0012, dated March 31, 2003). As described with respect to §26.199(f)(2), the NRC has received numerous allegations from nuclear security officers that certain licensees have required them to work excessive amounts of overtime over long periods due to the post-September 11, 2001, threat environment. These individuals questioned their readiness and ability to perform their required job duties because of the adverse effects of cumulative fatigue. The NRC reviewed the actual hours worked by security personnel and determined that, in the vast majority of cases, individual work hours did not exceed the guidelines specified in the NRC's Policy on Worker Fatigue. However, the review confirmed that individuals had been working up to 60 hours per week for extended periods. Individual concerns regarding their fitness for duty, in light of work schedules that did not exceed the specific guidelines of the policy, as well as relevant technical research

supporting the basis for cumulative fatigue, led the NRC to conclude that the work hour guidelines of the Policy are inadequate for addressing cumulative fatigue. The NRC obtained additional support for this conclusion following a review of worker fatigue concerns and work hours during a long-term outage at the Davis Besse nuclear plant (NRC Inspection Report 05000346/2004003, dated March 31, 2004, ADAMS Accession No. ML040910335).

Through public interactions during the development of Order EA-03-038, the NRC developed a collective work hour requirement, rather than a limit on individual work hours, in response to stakeholder input regarding differences among individuals in their abilities and desires to work overtime. Similarly, the proposed rule would permit a group of workers who are performing similar duties to average 48 hours of work over a period not to exceed 13 weeks [proposed requirements for calculating collective work hours are discussed with respect to proposed §26.199(b)(2)]. Because the proposed limit would be imposed on a job duty group's average number of work hours during an averaging period, licensees would continue to be permitted to distribute overtime among their workers based on their assessment of individuals' abilities and desires to work overtime. The proposed averaging methodology would not unduly limit individuals from working voluntary overtime, and would effectively result in adequate opportunities for days off and limited forced overtime. As discussed with respect to proposed §26.199(b)(2), requiring licensees to average collective work hours over a period up to 13 weeks in length would establish a limit on the long-term scheduling of work hours that would support timely identification and corrective action for conditions that could contribute to cumulative fatigue, but would not be overly sensitive to short-term variations in workload. Short-term variations in workload have limited potential for causing cumulative fatigue.

The NRC considered several types and sources of information in deciding to propose a collective work hour limit of 48 hours per person per week. These included: (1) past

recommendations from experts and expert panels on work scheduling and maintaining worker alertness in the nuclear industry; (2) surveys of nuclear power plant workers on their desire and ability to work overtime; (3) data on the amount of overtime worked by security personnel; and (4) the requirements and practices in other industries.

Two of the most comprehensive documents on worker fatigue in the U.S. nuclear industry are EPRI NP-6748 (Baker, et al., 1990) and NUREG/CR-4248. The collective work hour limit is a new concept developed to meet the NRC's objectives, while also addressing the unique circumstances and specific concerns of the stakeholders. As a consequence, neither of the documents provides specific guidelines for establishing collective work hour limits. Nevertheless, the documents contain information and guidelines relevant to the proposed requirement. Collectively, the shift scheduling guidelines of EPRI NP-6748 and NUREG/CR-4248 suggest a maximum routine work schedule of 44–46 hours per week. This maximum includes an assumed turnover time of 30 minutes per shift. The NRC also considered the recommendations of experts concerning the use of overtime. The expert panel that developed the guidelines for NUREG/CR-4248 also addressed use of overtime and recommended an individual limit of 213 hours per month, including shift turnover time. The expert panel emphasized that overtime should not be approved for an entire crew, indicating that this individual maximum on overtime should not be a group norm. The collective work hour limit of 48 hours per person per week would establish a requirement that is in the middle of the range of work hours defined by the maximum routine scheduling limits and maximum individual overtime, and also provides for individual differences with respect to vulnerability to fatigue. The expert panel further recommended that the NRC authorize no more than 400 hours of overtime in a year. A limit of 400 hours of overtime annually is very similar to a 48-hour average (i.e., 52 weeks x 8 hours = 416 hours).

In addition to considering the opinions of experts in work scheduling and fatigue, the NRC staff considered the opinions of individuals who work in nuclear power plants. These opinions were expressed in surveys conducted by PROS and EPRI.

In 2002, PROS surveyed the attitudes of its members towards work hours and the development of a proposed rule concerning fatigue of workers at nuclear power plants (ADAMS Accession No. ML05270310). One of the survey questions was, “What is your personal tolerance for overtime?” The responses indicated that 75 percent of the respondents had a “tolerance” for up to 350 hours per year. Only 13 percent expressed a tolerance for more than 350 hours of overtime.

The work conducted in the development of EPRI NP-6748 also included a survey of operators. The results were consistent with the PROS survey, indicating that the amount of overtime that operators wanted to work ranged from 100 to 400 hours per year. Similar results were obtained in a survey of nuclear power plant personnel in the United Kingdom.

A 48 hour per person per week collective work hour limit would permit job duty groups to average approximately 400 hours of overtime, or 2400 hours of work, in a year. Therefore, the proposed collective work hour limit would be consistent with the upper extreme of overtime hours for which nuclear power plant personnel have expressed a tolerance. In addition, the proposed collective work hour limit would be less restrictive than the limit implied by worker opinions because the 48-hour average would exclude hours worked during the first 8 weeks of outages.

In addition to expert and worker opinions, the NRC considered industry practices concerning the use of overtime for security personnel. The NRC collected work scheduling data for security personnel at all nuclear power plants following the events of September 11, 2001, as part of the process of evaluating the need to require licensees to

implement compensatory measures to address security personnel fatigue. The NRC's analysis, as described in letters from the NRC to licensees (e.g., ADAMS Accession No. ML031880257), indicated that at some of the sites (31 percent), security personnel worked more than 55 hours per week and at a few sites (11 percent) they worked 60 hours or more per week. The data also indicated that at the majority of the sites (58 percent) security personnel typically worked 50 hours per week or fewer. The NRC also reviewed work hours data collected by NEI (ADAMS Accession No. ML003746495) and found that, although there was substantial variation among sites, the average annual overtime for licensed operators was 375 hours and 361 hours for non-licensed operators. These findings suggest that an average work week of 48 hours is an achievable objective for security personnel as well, although it was not a current practice at a small fraction of nuclear power plants.

The proposed 48-hour per person per week collective work hour limit would be comparable to restrictions on workers in other industries within the U.S. and the limits imposed by other countries that regulate overtime for nuclear power plant workers. The NRC staff considered that cumulative fatigue of nuclear power plant personnel is addressed in several other countries through individual monthly and/or annual work hours limits on overtime. These limits, summarized in Table 6 of Attachment 1 to SECY-01-0113, are generally more restrictive than the proposed 48-hour collective work hour limit because they permit fewer hours of work and provide less flexibility because the limits apply to individuals rather than groups (e.g., Finland limits overtime to 250 hours per year). Table 5 of Attachment 1 to SECY-01-0113 includes a summary of limits on work hours in other industries in the U.S.

The NRC also considered the requirements of the European Union (EU) Working Times Directive (WTD) (Council Directive, 1993). The WTD establishes requirements concerning the working hours of workers across various industries in EU member nations. The WTD

establishes a requirement that “workers cannot be forced to work more than 48 hours per week averaged over 17 weeks.”

In addition, the amount of overtime permitted by the proposed 48-hour collective work hour limit would be greater than the amount used in most continuous operations. Circadian Technologies Incorporated, a consulting firm that is expert in fatigue management, regularly surveys U.S. and Canadian companies conducting 24/7 operations. Their 2000 survey of 550 major companies indicates that shift workers at 89 percent of the companies surveyed averaged less than 400 hours of overtime per year (Circadian Technologies Incorporated, 2000). Circadian Technologies Incorporated noted that average overtime for workers in extended operations in the U.S. was 12.6 percent above the standard work-week in the first 8 months of 2003, with utilities averaging 14.9 percent (Circadian Technologies Incorporated, 2003).

Therefore, the proposed 48-hour collective work hour requirement would establish an appropriate upper limit on work hours while the plant is operating. The proposed limit would be consistent with expert and worker opinions concerning work hours, provide substantial licensee flexibility, and recognize individual differences in the ability to work overtime while remaining fit to safely and competently perform duties.

Proposed §26.199(f)(1) would be added to exclude the first 8 weeks of plant outages from the collective work limit in proposed §26.199(f) for the job duty groups that are specified in proposed §26.199(a)(1)–(a)(4) (i.e., certain operations, maintenance, chemistry, health physics, and fire brigade personnel). During the first 8 weeks of a plant outage, proposed §26.199(d) would require these individuals to be subject to individual work hour controls. After the first 8 weeks of a plant outage, proposed §26.199(f)(1) would require licensees to resume controlling

the work hours of these individuals in accordance with the collective work hour limit in proposed §26.199(f).

The collective work hour limits of proposed §26.199(f) would address the long-term control of work hours while permitting the occasional use of limited overtime for circumstances such as equipment failure, personnel illness, or attrition. The NRC proposes to address the control of work hours during short- and medium-length outages separately and permit licensees to waive the collective work hour controls for the first 8 weeks of an outage in proposed §26.199(f)(1). In developing the proposed permission to exclude the first 8 weeks of an outage from the collective work hour limits, the NRC considered several factors, including current policy, the bases for the policy, and lessons learned from the policy implementation.

The NRC's Policy on Worker Fatigue provides guidelines for controlling work hours, "on a temporary basis," during periods requiring substantial overtime. The Policy reflects the NRC's recognition that outages are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. The policy also reflects the NRC's understanding that, although individuals are capable of working with limited rest without degraded performance for short periods of time, research has shown that the ability to sustain performance without adequate rest is clearly limited (Knauth and Hornberger, 2003; Pilcher and Huffcutt, 1996; Van Dongen, et al., 2003), as discussed in Section IV. D. However, as noted in SECY-01-0113, Attachment 1, the NRC has never defined the term, "temporary basis," as used in the Policy. As a result, licensees have relied on this phrase in the guidelines to permit extended work hours for periods ranging from a few days to more than a year. Industry experience with conditions such as sustained plant shutdowns and the increased work hours of security personnel following the terrorist attacks of September 11, 2001, have demonstrated the

need for the NRC to establish clearer and more readily enforceable requirements limiting the sustained use of extended work hours.

Differences between individuals, job demands, and work-rest schedules can each have a substantial effect on the period of time that an individual can work without compromising his or her ability to safely and competently perform duties. As a result, studies of work scheduling and fatigue provide insights into the potential for cumulative fatigue of workers, but do not provide a direct basis for establishing the maximum acceptable period for excluding plant outage work hours from the collective work hour controls. In setting the exclusion period for plant outages at 8 weeks, the NRC considered that, by the end of 8 weeks of work at the limits permitted by proposed §26.199(d), individuals who are performing the duties specified in proposed §26.199(a)(1)–(a)(4) will have (1) worked 540 hours, including more than 200 hours of overtime, and (2) missed as many as 17 normally scheduled days off. The loss of the 17 normally scheduled days off would be a reduction of 60 percent in the time available to recover and prevent cumulative fatigue. Further, with each passing week of an outage involving increased work hours and decreased time off, deferring daily living obligations becomes increasingly difficult, causing increased pressure on individuals to reduce their sleep time in order to meet the demands of both work and daily life, resulting in an increased potential for cumulative fatigue.

In addition to considering the potential for cumulative fatigue, the NRC considered current industry data on the duration of plant outages in determining whether the cost to licensees imposed by the proposed 8-week outage exclusion period are justified in terms of the benefit. The average outage duration, as indicated by outage data from 2000-2002, is approximately 39 days (Information System on Occupational Exposure Database, ADAMS Accession No. ML050190016). Eighty-nine percent of plant outages during this period were

less than 8 weeks in duration. In reviewing the frequency of outages, by duration, the NRC found that it would be necessary to increase the exclusion period substantially to address a marginal number of additional outages of longer lengths. This increase in the exclusion period would substantially increase the period of time that work hours would not be controlled by the proposed 48-hour collective work hour limit, which would be the proposed rule's principal requirement to prevent cumulative fatigue. During the exclusion period, individuals would only be assured of a 24-hour break every 7 days and a 48-hour break every 14 days, under the individual work hour limits in proposed §26.199(d)(1) and (d)(2). Individuals who work 12-hour shifts would average 66 hours per week, a rate of more than 150 percent of their normally scheduled hours with less than half of their normally scheduled days off for recovery, for a period that would exceed 2 months. These extended work hours would substantively increase the potential for cumulative fatigue and fatigue-related personnel errors. By contrast, decreasing the exclusion period to less than 8 weeks would increase the number of outages that would be, in part, subject to the collective work hour controls, potentially increasing the duration and cost of those outages. Decreasing the exclusion period by 1 or 2 weeks could also decrease the potential for cumulative fatigue, but the magnitude of the decrease would be difficult to quantify and the benefit would unlikely justify the costs.

Excluding the first 8 weeks of an outage would be consistent with the NRC's objective of ensuring that licensees provide adequate shift coverage without routine heavy use of overtime. The proposed exclusion period would be limited to plant outages, which occur regularly, but with limited frequency. In addition, the proposed rule would limit the duration of the exclusion period to 8 weeks in order to limit the potential for cumulative fatigue.

Proposed §26.199(f)(2)(i) would be added to establish a collective work hour limit of 60 work hours per person per week for personnel who are performing the job duties specified in

proposed §26.199(a)(5) (i.e., security personnel) during the first 8 weeks of a plant outage or a planned security system outage. The proposed rule would permit a 60-hour per person per week collective work hour limit as an exception to the 48-hour collective work hour limit in proposed §26.199(f). The proposed exception for security personnel would accommodate the short-term demand for increased work hours associated with these outages while limiting cumulative fatigue. Therefore, the proposed requirement would provide reasonable assurance that security personnel would remain capable of safely and competently responding to a security incident or an increased security threat condition, should one occur during or shortly after a period of increased work hours.

The basis for excluding work hours during the first 8 weeks of an outage from the proposed requirement for a 48-hour group average is discussed with respect to proposed §26.199(f)(1). However, that exclusion would be only applicable to individuals who are performing the duties listed in proposed §26.199(a)(1)–(a)(4) during plant outages. During the first 8 weeks of a plant outage, those individuals would remain subject to the proposed individual work hour controls but their work hours would not be limited by any collective work hour requirement. By contrast, proposed §26.199(f)(2)(i) would require security personnel to be subject to a 60-hour per person per week collective work hour limit, in addition to the proposed individual work hour limits, during the first 8 weeks of a plant outage.

Proposed §26.199(f)(2)(i) also would permit licensees to exclude security personnel from the 48-hour per person per week collective work hour limit during the first 8 weeks of a planned security system outage, during which time they would be subject to a 60-hour per person per week collective work hour limit. Planned security system outages are typically of very short duration (days), and the NRC does not expect that planned security system outages will exceed 8 weeks in length. However, the proposed rule would establish the 8-week limit for

planned security system outages in order to simplify implementation of the rule by applying identical exclusion periods for all outages and increased threat conditions. Additionally, the ability of security personnel to safely and competently perform their duties during these varying outages and increased threat conditions is based on the length of time individuals work additional overtime, not on the nature of the site condition.

The proposed provision would codify, in part, requirements established by Order EA-03-038, although it would limit the exclusion period to 8 weeks instead of the 120-day exclusion period that is permitted in Order EA-03-038, for the reasons discussed above. Since September 11, 2001, the NRC has received reports of nuclear security officers found asleep while on duty. In addition, the NRC received numerous allegations from nuclear security officers that certain licensees have required them to work excessive amounts of overtime over long periods due to the post-September 11 threat environment. The nuclear security officers questioned their readiness and ability to perform their required job duties because of the adverse effects of cumulative fatigue and stated that they feared reprisal if they refused to work assigned overtime. The NRC received similar information from newspaper articles and from interactions with public stakeholder groups. For example, the Project on Government Oversight (POGO) issued a report entitled, “Nuclear Power Plant Security: Voices from Inside the Fences,” and submitted this report to the NRC staff (ADAMS Accession No. ML031670987). POGO interviewed more than 20 nuclear security officers protecting 24 nuclear reactors (at 13 plants) to obtain material for its report. POGO reported that the security officers who were interviewed said, “Their plants are heavily relying on increased overtime of the existing guard force...These guards raised serious concerns about the inability to remain alert.” After reviewing the work hours and FFD concerns of security personnel subsequent to September 11, 2001, the NRC issued Order EA-03-038 to limit the work hours of security

personnel and ensure that they remain capable of safely and competently performing their duties. The Order required compensatory measures for limiting work hours to a collective work hour average of 48 hours per person per week during normal operations, as well as limiting work hours to an average of 60 hours per week for planned plant outages and planned security system outages.

Ensuring that work schedules incorporate adequate break periods is an important mitigation strategy for cumulative fatigue. The NRC's initial concept for compensatory measures to prevent fatigue of security personnel from the long work hours of outages included a feature that required a 48-hour break in any 7-day period for periods of elevated overtime that exceeded 45 days (ADAMS Accession No. ML030300470). Through stakeholder interactions during development of the Order, the NRC concluded that a 60-hour collective work hour limit would be an effective alternative to meet the same objective and also provided more flexibility. The proposed 60-hour limit would ensure that security force personnel who work a 12-hour shift receive, on average, 2 days off in every 7-day period, thereby reducing the potential for cumulative fatigue. The need for periodic long breaks was discussed with respect to proposed §26.199(d)(2)(ii) and (d)(2)(iii).

For several reasons, control of work hours for security personnel must be more stringent than for other individuals who would be subject to the proposed work hour controls. First, security personnel are the only individuals at nuclear power plants who are entrusted with the authority to apply deadly force. Decisions regarding the use of deadly force are not amenable to many of the work controls (e.g., peer checks, independent verification, post-maintenance testing) that are implemented for other personnel actions at a nuclear plant to ensure correct and reliable performance. Second, unlike most other work groups, security personnel are typically deployed in a configuration such that some have very infrequent contact with other

members of the security force, or other plant personnel. A lack of social contact can exacerbate the effects of fatigue on individuals' abilities to remain alert (Horne, 1988). Third, these deployment positions can be fixed posts where very little physical activity is required, further promoting an atmosphere in which fatigue could transition into sleep. Fourth, many security duties are largely dependent on maintaining vigilance. Vigilance tasks are among the most susceptible to degradation from fatigue (Rosekind, 1997; Monk and Carrier, 2003). Finally, unlike operators, security forces lack automated backup systems that can prevent or mitigate the consequences of an error caused by fatigue.

The proposed requirement would also differ from that in Order EA-03-038 by requiring licensees to meet 60-hour per person per week collective work hour limit during unplanned plant outages. Order EA-03-038 currently does not impose collective work hour limits for these conditions. As discussed in the preceding paragraph, security duties are particularly susceptible to fatigue. Therefore, the NRC considers that the proposed 60-hour per person per week collective work hour limit for security personnel should only be waived in cases in which: (1) licensees would be unable to sufficiently plan for the increased security demands; and (2) the increased potential for fatigue-induced errors is outweighed by the need for a higher complement of security personnel on shift to maintain the common defense and security. In the case of unplanned security system outages, although licensees would be unable to sufficiently plan for the increased security demands that typically accompany plant outages, the increase in those demands is directly due to the need to return the plant to operation (such as additional guards needed to support maintenance activities), not the need to maintain the common defense and security (as is the case with security system outages). The increased potential for fatigue-induced errors under the greatly increased work hours that would be permitted in the

absence of collective work hour controls could not be justified by the economic benefit gained by licensees.

Proposed §26.199(f)(2)(ii) would be added to establish a collective work hour limit of 60 hours per person per week for security personnel during the actual conduct of Force-on-Force (FOF) exercises. The proposed rule would include a 60-hour per week collective work hour limit for security personnel as an exception to the 48-hour collective work hour limit in proposed §26.199(f). The proposed exception would accommodate the short-term demand for increased work hours associated with FOF exercises while limiting cumulative fatigue, thereby providing reasonable assurance that security personnel will remain capable of safely and competently responding to a security incident or increased threat condition, should one occur during or shortly after the conduct of FOF exercises. The basis for requiring security personnel to be subject to a 60-hour per person per week collective work hour limit, in addition to the individual work hour limits, in lieu of waiving the group average limits completely, is discussed with respect to proposed §26.199(f)(2)(i).

The proposed 60-hour collective work hour limit during FOF exercises would be consistent with the relaxation to Order EA-03-038, granted October 23, 2003. During public meetings concerning Order EA-03-038, industry stakeholders commented that the FOF exercises warrant special consideration because NRC participation in the exercises causes some aspects of the exercises to be outside industry control, and because of the short-term and unique staffing demands imposed on licensees during the exercises. In addition, industry stakeholders have commented that: (1) hiring extra security officers for such short-term demands would be inefficient and injurious to workforce stability; (2) imposing a staffing level requirement on licensees sufficient to support the FOF exercises would result in staff levels greater than those routinely needed; and (3) the benefit of conducting these exercises far

outweighs the additional burden of the person-hours expended. The NRC agrees that the conduct of the pilot and annual FOF exercises warrant special consideration because: (1) the benefits of conducting a FOF exercise outweigh concerns regarding work-hour limits; (2) the exercises are infrequent and intensive efforts conducted over a short-term period; and (3) the burden to meet the significant staffing demands during the exercises would be very high if work hours were limited to a collective average of 48 hours per person per week.

Proposed §26.199(f)(2)(iii) would be added to provide an exception to the collective work hour limits for security personnel for the first 8 weeks of an unplanned security system outage or an increased threat condition. The proposed exception would codify, in part, the compensatory measures required by Order EA-03-038. However, Order EA-03-038 provides an exception from the collective work hour limits in the compensatory measures for these conditions for a period up to 120 days. Proposed §26.199(f)(2)(iii) would establish a more stringent exception period.

Unplanned security system outages and increased threat conditions require extensive increases in security force labor in terms of compensatory measures. These increases can make it very difficult to maintain work hour controls during these periods, especially because licensees are unable to plan in advance for these circumstances. Although the increased work hours increase the potential for cumulative fatigue, other proposed fatigue management requirements, including the individual work hours controls in proposed §26.199(d)(1) and (d)(2), would provide reasonable assurance of guard readiness during the exception period. Therefore, the benefit to plant security of ensuring adequate staffing during such unplanned conditions would outweigh the potential for excessive worker fatigue.

Staffing to maintain work hours within the limits of the proposed collective work hour controls would not be practical because it would require licensees to maintain security staffing

at levels that would be excessive for the vast majority of circumstances. Limiting periods of extended work hours for security personnel to 8 weeks brings security personnel closer to the requirements for the other proposed exclusion periods, simplifying the rule and its implementation. Further, the cost to licensees of the compensatory measures required to address security system outages is significant, and most security systems are modular. Therefore, an unplanned security system outage is unlikely to exceed 8 weeks. Outages of this duration have been uncommon. Therefore, reducing the exclusion period from 120 days to 8 weeks would be unlikely to have a practical impact on licensees.

In the case of an increased threat condition, the Department of Homeland Security has refined their threat system to compartmentalize increases in threat conditions for individual business sectors and regions of the country. Also, since the inception of the system, there has never been an increase for any period that exceeded 6 weeks. An event that would cause NRC-regulated sites to adopt an increase over 8 weeks would likely mean a significant domestic attack had occurred. In this event, proposed §26.199(f)(5) would provide a means for extending the proposed 8-week exclusion period, as discussed with respect to that provision.

Proposed §26.199(f)(2)(iv) would be added to clarify the instances in which security personnel would be subject to a collective work hour limit for certain instances in which multiple plant conditions exist. As discussed with respect to proposed §26.199(f)(2)(iii), licensees would not be required to control the collective work hours of security personnel during the first 8 weeks of an increased threat condition. Proposed §26.199(f)(2)(iv) would establish requirements for implementing this exception should an increased threat condition occur concurrently with a plant outage or planned security system outage. The proposed exception would codify, in part, an exception to group work hour controls permitted by Order EA-03-038.

As would be required by proposed §26.199(f)(2)(i), the collective work hours of security personnel would be limited to an average of not more than 60 hours per person per week during any plant outage or planned security system outage. If an increase in threat condition occurs during such a period, and the increased threat condition persists for a period of 8 weeks or fewer, proposed §26.199(f)(iv) would establish an exception for the collective work hour controls on security personnel for the duration of the increased threat condition. However, if during any such outage, the threat condition returned to the least significant threat condition that was in effect at any time within the past 8 weeks, then the licensee would be required to limit the collective work hours of security personnel to an average of 60 hours per person per week for the first 8 weeks of the outage for the periods that occurred before and after the increased threat condition. For example, if, during an 8-week outage, the threat level increased at the beginning of week 3 and returned to the original or a lower threat level at the conclusion of week 4, then the licensee would be required to limit the collective work hours of security personnel to a group average of no more than 60 hours per person per week during weeks 1–2 and 5–8 of the outage. Outage weeks 3–4 would not be subject to the proposed work hour controls because of the increased threat condition. As such, proposed §26.199(f)(2)(iv) would clarify the limits to be applied when multiple plant conditions occur at the same time. Consistent with the requirements of proposed §26.199(f)(2)(i), licensees would be required to limit the collective work hours of security personnel to an average of 48 hours per person per week following the first 8 weeks of the outage.

This proposed exception to the collective work hour controls would be necessary to ensure that licensees have the flexibility to take any immediate actions necessary for maintaining plant security. The proposed exception would be limited in duration to ensure that

licensees take appropriate long-term actions to prevent cumulative fatigue should the increased threat condition be sustained for a period that is longer than 8 weeks.

Proposed §26.199(f)(2)(v) would be added to further clarify the applicability of the collective work hour limits for security personnel during multiple consecutive and concurrent plant conditions. Licensees would be permitted to relax collective work hour controls in situations in which additional increases in threat condition occur during an unplanned security system outage or increased threat condition, but only for a period that is the shorter of either the duration of the increased threat condition or 8 weeks. The proposed exception would codify, in part, an exception to collective work hour controls that is permitted by Order EA-03-038. The proposed exception to the collective work hour controls would be necessary to ensure that licensees have the flexibility to take any immediate actions necessary for maintaining plant security in response to increasing security threat levels. The proposed exception would be limited in duration to ensure that licensees take appropriate long-term actions to prevent cumulative fatigue should an increased threat condition be sustained for a period of more than 8 weeks.

Proposed §26.199(f)(2)(vi) would be added to establish requirements controlling the exception period from the collective work hour controls when a threat condition decreases during an unplanned security system outage or increased threat condition. In these circumstances, the proposed rule would establish the beginning of the exception period based upon the date upon which the current threat condition was last entered as a result of a threat condition increase. For example, if the threat level increases at the beginning of week 1, increases again at the beginning of week 3, and then decreases in week 5, the beginning of the maximum 8-week exception period would be the beginning of week 1. The proposed requirement would ensure that the duration of the exception period is no longer than necessary

based upon the current threat level, thereby providing licensees with the flexibility to respond to increased threat conditions while minimizing the potential for cumulative fatigue of security personnel. Proposed §26.199(f)(2)(vi) would codify, in part, an exception to the work hour controls that is permitted by Order EA-03-038.

Proposed §26.199(f)(3) would be added to permit the collective work hours of any job duty group specified in proposed §26.199(a) to exceed an average of 48 hours per week in one averaging period if all of the conditions specified in proposed §26.199(f)(3)(i)–(f)(3)(iii) are met. The collective work hour controls of proposed §26.199(f) would address the long-term control of work hours, including the limited use of overtime for occasional, short-term, exigent circumstances. The primary objective of proposed §26.199(f) would be to ensure that fatigue resulting from the routine work hours of individuals performing the functions listed in proposed §26.199(a)(1)–(a)(5) would not adversely affect their abilities to safely and competently perform their duties, and therefore that licensees maintain adequate shift coverage without routine heavy use of overtime. The objective of proposed §26.199(f)(3) would be to establish a regulatory framework that would accommodate circumstances beyond the reasonable control of licensees, while ensuring that licensees continue to provide reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety. The criteria in proposed §26.199(f)(3)(i)–(f)(3)(iii) would permit licensees to control work hours to a higher collective work hour limit under certain occasional, short-term, exigent circumstances.

Proposed §26.199(f)(3)(i) would be added to establish the first criterion for permitting a higher collective work hour limit by requiring that the circumstances that cause collective work hours to exceed 48 hours per person per week cannot be reasonably controlled. Unusual

circumstances (e.g., strikes, hurricanes, outage extensions for reasons that licensees cannot reasonably control, extremely high employee turnover) may require increased work hours for a short period of time, and licensees cannot practically maintain staffing reserves to avoid using overtime in such unusual circumstances. These unusual circumstances would place licensees in jeopardy of violating the requirements of proposed §26.199(f). However, temporarily exceeding the proposed collective work hour limits in circumstances that could not be reasonably controlled by a licensee generally would not indicate that the licensee's fatigue management program was ineffective.

Proposed §26.199(f)(3)(ii) would be added to establish the second criterion for permitting a higher collective work hour limit in unusual circumstances that could not be reasonably controlled. The proposed rule would prohibit collective work hours from exceeding 54 hours per person per week in these circumstances. This proposed limit would be necessary to ensure that workers do not become unacceptably fatigued during the exigent circumstances. In some instances, licensees may rely on this provision to permit a 54-hour per person per week collective work hour limit during the averaging period following an 8-week outage that was extended for reasons beyond the licensee's reasonable control (e.g., defects in new equipment that were only detectable following installation, late delivery of key equipment or parts). Limiting collective work hours to 54 hours per person per week would provide a substantial increase in the hours that would be available to address the emergent circumstance(s) [equivalent to approximately one month of work at the maximum hours permitted by the individual work hours controls of proposed §§26.199(d)(1) and (d)(2)] while continuing to ensure the availability of some recovery days.

Proposed §26.199(f)(3)(iii) would be added to establish the third criterion for permitting a higher collective work hour limit. The proposed rule would require that the additional work

hours that result in the group average exceeding 48 hours per person per week would be worked only to address the circumstances that the licensee could not have reasonably controlled. This proposed provision would require licensees to use relief from the 48-hour collective work hour limit only to the extent necessary, and not as an opportunity to increase work hours for unrelated activities performed by the group. For example, the proposed provision would permit a maintenance job duty group's collective work hours to average 50 hours per person per week in one averaging period if a crew of maintenance technicians worked excess hours in order to exit an LCO on time. However, the proposed provision would not permit the licensee to assign unrelated work activities to other maintenance technicians, and thereby increase the group's collective work hours to the 54 hours per person per week that the proposed rule would permit in the specified circumstances.

Proposed §26.199(f)(4) would be added to prohibit licensees from repeatedly permitting the collective work hours of any job duty group to exceed an average of 48 hours per person per week. As discussed with respect to proposed §26.199(f)(3), the NRC recognizes that, because of circumstances that a licensee cannot reasonably control, there may be averaging periods in which a job duty group's collective work hours exceed the 48-hour collective limit. However, the primary objective of the collective work hour limit would be to prevent cumulative fatigue that can result from sustained extended work hours. The repeated use of the accommodations afforded by proposed §26.199(f)(3) to exceed the 48-hours per person per week collective work hour limit in proposed §26.199(f) would be inconsistent with the objective of preventing cumulative fatigue. Both increased workload and decreased opportunity for rest can contribute to cumulative fatigue (Baker, et al, 1994; Rosekind, 1997; Totterdell, et al, 1995; Knauth and Hornberger, 2003; Rosa, 1995). With each passing week of an extended work schedule, individuals have worked an increasing number of their normally scheduled days off.

Deferring daily living obligations becomes increasingly difficult, causing increased pressure to reduce sleep time in order to meet the demands of both work and daily life, thereby increasing the potential for cumulative fatigue. Therefore, it would be necessary to ensure that licensees do not permit any job duty group to exceed the collective work hours limits in the proposed rule repeatedly.

Proposed §26.199(f)(4)(i) would be added to prohibit licensees from permitting the collective work hours of any job duty group to exceed the 48-hour limit in any two consecutive averaging periods. This proposed requirement would ensure that individuals in a job duty group who worked extended hours during one averaging period have recovery time during the subsequent averaging period, during which they would resume working normal work hours.

Proposed §26.199(f)(4)(ii) would prohibit licensees from permitting the collective work hours of any job duty group to exceed the 48-hour limit in more than one averaging period during any 26-week period. This proposed requirement would be necessary because the proposed rule permits licensees to establish averaging periods of any length less than 14 weeks in proposed §26.199(b)(2) [Collective work hours]. By manipulating the lengths of averaging periods, for example, a licensee could require a job duty group to work hours in excess of the 48-hour collective limit during one 13-week averaging period, reduce the group's collective work hours to 48 hours or fewer during a subsequent 1-week averaging period, and still be in compliance with proposed §26.199(f)(4)(ii). This schedule manipulation could result in individuals working 48 weeks of extended work hours in a calendar year, punctuated only by four, 1-week periods of normal work hours, which would lead to extreme levels of cumulative fatigue. Therefore, in order to ensure that the 48-hour collective work hour limit achieves the objective of preventing cumulative fatigue, proposed §26.199(f)(4)(ii) would require that any

averaging periods in which a job duty group works extended hours during normal operations would be widely separated in time and occur no more frequently than twice in one rolling year.

Proposed §26.199(f)(5) would be added to permit licensees to exceed any collective work hour limit of proposed §26.199(f) if the licensee submits a written request to the NRC and obtains advance approval of a written request that includes the information in proposed §26.199(f)(5)(i)–(f)(5)(iii). Proposed §26.199(f)(5) would provide a regulatory framework for addressing unique and infrequent circumstances, such as steam generator replacements or other extended outages, that would be difficult to manage within the collective work hour controls of proposed §26.199(f), but that licensees could effectively manage using comparable work scheduling controls and fatigue mitigation strategies. For example, an extended outage of longer than 8 weeks may have a high workload at the beginning and end of the outage, with limited use of extended hours in the intervening period. The potential for cumulative fatigue may be minimal in such circumstances. However, the use of extended work hours after the first 8 weeks of the outage would be subject to collective work hour controls and could challenge the ability of the licensee to limit collective work hour averages to no more than 48 hours per person per week in the subsequent averaging period. Proposed §26.199(f)(5) would permit licensees to obtain approval for alternative approaches to work scheduling controls and fatigue mitigation strategies that the licensee could tailor to these unique and infrequent circumstances.

Proposed §26.199(f)(5)(i) would be added to require that the written request to the NRC must include a description of the specific circumstances that would require the licensee to exceed the applicable collective work hour limit, the job duty group(s) affected, and the collective work hours limit(s) to be exceeded. The information regarding the specific circumstances would be necessary for the NRC to determine whether the circumstances warrant special consideration and whether the fatigue mitigation strategies that the licensee

would be required to establish in proposed §26.199(f)(5)(iii) would be appropriate for those circumstances. The information on the job duty group(s) affected would be necessary for the NRC to determine whether the licensee's proposed fatigue mitigation strategies are appropriate for those job duty group(s) and also to ensure that NRC resident inspectors would be aware of which job duty group(s) would be working under the revised work hour controls, if approved. Information on the collective work hour limit(s) to be exceeded would be necessary for the NRC to evaluate whether the fatigue mitigation strategies would provide an effective alternative to the limit(s) to be exceeded.

Proposed §26.199(f)(5)(ii) would be added to require the written request to include a statement of the period of time during which it would be necessary to exceed the collective work hour limit(s). This information would be necessary for the NRC to evaluate whether the fatigue mitigation strategies that the licensee would be required to establish in proposed §26.199(f)(5)(iii) are appropriate for the time period requested.

Proposed §26.199(f)(5)(iii) would be added to require the written request to include a description of the fatigue mitigation strategies, including, but not limited to, rest break requirements and work hour limits, that the licensee would implement to ensure that the individuals affected would be fit to safely and competently perform their duties. This information would be necessary for the NRC to evaluate whether these strategies would provide an effective alternative to the work hour limits to be exceeded.

Proposed §26.199(g) [Successive plant outages] would be added to establish requirements for the control of work hours during plant outages that closely follow a preceding plant outage. At the conclusion of an outage, individuals are likely to be fatigued from working extended hours and the increased workload associated with the outage and plant restart preparations. The objective of the proposed requirement would be to provide adequate

opportunity for individuals to recover and transition to an operating schedule, and thereby reduce the potential for cumulative fatigue of individuals that can result from outages that occur in close succession. The proposed requirement would apply to outages that follow the preceding outage by less than 2 weeks. A minimum of 2 weeks under normal workloads and the collective work hour requirements of proposed §26.199(f), which are generally only applicable during non-outage periods, would be necessary to provide reasonable assurance that individuals have the opportunity for successive days of rest to reduce the potential for cumulative fatigue. For purposes of work hour control, the proposed provision would require licensees in effect, to treat outages that follow a preceding outage by less than 2 weeks as a continuation of the first outage. Specifically, licensees would be required to apply the requirements of proposed §26.199(d)(2)(iii), (f)(1), (f)(2)(i), and (f)(2)(iv) based upon the number of days that have elapsed since the first plant outage in the series began. For example, if a refueling outage lasts 6 weeks, but the plant encounters difficulties during power ascension a day after exiting the refueling outage, and enters a new outage, then the 8-week exclusion period must be calculated from the beginning of the refueling outage.

Proposed §26.199(h) [Common defense and security] would be added to relieve a licensee from the proposed collective work hour controls when written notification is received from the NRC for the purpose of assuring the common defense and security for a period defined by the NRC. This proposed paragraph would provide necessary relief from the requirements of this proposed section in cases of emergencies that are not otherwise covered in this section, including war, in which the increased risk from fatigue-induced errors would be outweighed by the need to maintain the common defense and security. The proposed provision would define the process by which the NRC would provide such relief.

Proposed §26.199(i) [Plant emergencies] would be added to temporarily waive the requirements of proposed §26.199(c)–(f) during declared emergencies, as defined in the licensee's emergency plan. Plant emergencies are extraordinary circumstances that may be most effectively addressed through staff augmentation that can only be practically achieved through the use of work hours in excess of the limits of proposed §26.199(c)–(f). The objective of the proposed temporary exemption would be to ensure that the control of work hours and management of worker fatigue do not impede a licensee's ability to use whatever staff resources may be necessary to respond to a plant emergency and ensure that the plant reaches and maintains a safe and secure status. At the conclusion of the declared emergency, the proposed rule would require licensees to again comply with the work hour controls.

Proposed §26.199(j) [Reviews] would be added to require licensees to periodically self-assess their performance with respect to controlling the work hours of those individuals who perform the job duties specified in proposed §26.199(a). The work hour controls in proposed §26.199(a) would provide licensees with substantial flexibility in controlling work hours. Accordingly, periodic self-assessments would be necessary to maintain reasonable assurance that the licensee is implementing the specific work hour control provisions of proposed §26.199 consistent with the general performance objective in proposed §26.23(e). In addition, it would be necessary for the self-assessments to be scheduled in a manner that would ensure timely corrective action, if necessary. Outages and increased threat conditions increase the risk of human error as a result of higher workload, the performance of more complex and infrequent tasks, and the pressure to meet schedular goals. Therefore, it would be particularly important to include those periods of time in any assessment of the effectiveness of a licensee's work hour controls.

Proposed §26.199(j)(1) would be added to require licensees to focus their assessments on those individuals who were at the greatest risk of committing performance errors, including, but not limited to, those individuals listed in proposed §26.199(j)(1)(i)–(j)(1)(iv). These individuals would have worked the most hours when compared with their peers during the same averaging period; have been granted the most work-hour waivers; and were subject to fatigue assessments under proposed §26.201 (i.e., were assessed for fatigue for cause, post-event, or in response to a self-declaration of being unfit for duty because of fatigue). Requiring licensees to consider individual performance, as indicated by operating events or other errors, for those individuals listed in proposed §26.199(j)(1)(i)–(j)(1)(iii), would provide an indication of whether those individuals' abilities to safely and competently perform their duties had actually been compromised.

Proposed §26.199(j)(1)(i) would be added to require the assessments to include individuals who were granted more than one waiver during the review period. The proposed provision would require licensees to assess the work hours and performance of these individuals to ensure that licensees evaluate whether the individuals' abilities to safely and competently perform their duties had actually been compromised. The proposed requirement would be necessary to ensure that licensees' use of waivers did not result in degraded worker fitness-for-duty.

Proposed §26.199(j)(1)(ii) would be added to require the assessments to include individuals who were assessed for fatigue in accordance with §26.201 [Fatigue assessments] during the review period. The proposed paragraph would require licensees to evaluate whether these individuals' abilities to safely and competently perform their duties had actually been compromised. An individual who has been assessed for fatigue may be working above his or her tolerance for overtime, and it would be necessary for licensees to fully evaluate the

individual's overall performance. The proposed requirement would be necessary to ensure that licensee fatigue assessments are consistent with worker performance and are providing an effective basis for licensee fatigue management decisions.

Proposed §26.199(j)(1)(iii) would be added to require the assessments to include individuals who performed the job duties listed in proposed §26.199(a) whose average individual work hours per week exceeded 54 hours during any averaging period for which the collective work hours limit would be 48 hours in this proposed section. These individuals worked significantly more hours than others in their job duty group. The proposed requirement would be necessary to ensure that licensees fully evaluate the work hours and performance of these individuals, who are at a much higher risk for cumulative fatigue than their peers. As noted with respect to proposed §26.199(j)(1)(iii), several studies have indicated a tendency for individuals to underestimate their levels of fatigue (Wylie, et al., 1996; Dinges, 1995; Rosekind and Schwartz, 1988). This tendency may cause an individual to fail to recognize that his or her ability to perform is degraded. The proposed rule would require licensees to independently evaluate the performance of these individuals to determine whether their abilities to safely and competently perform their duties had actually been compromised.

Proposed §26.199(j)(1)(iv) would be added to require that the assessments must include security personnel whose average individual work hours per week exceeded 66 hours in any averaging periods for which the collective work hour limit in this proposed section would be 60 hours per person per week. The proposed rule would require licensees to evaluate the work hours and performance of these individuals for the same reasons discussed with respect to the individuals who would be evaluated under proposed §26.199(j)(1)(iii).

Proposed §26.199(j)(2) would be added to require licensees to review individuals' hours worked and the waivers under which work was performed to assess staffing adequacy for all of

the jobs that are subject to the work hour controls of proposed §26.199. The proposed collective work hour controls of §26.199(f) would provide assurance that licensees are managing cumulative fatigue at a gross level for broad job duty groups, and an indication of whether staffing is adequate to support this objective. However, the use of broad job duty groups creates a potential that sub-groups of individuals (e.g., those with specialized skills) may work a disproportionate number of hours and, consequently, may be more susceptible to fatigue than otherwise indicated by the collective averages. Accordingly, proposed §26.199(j)(2) would require licensees to review work hours and waivers of the work hour controls to provide assurance that cumulative fatigue is properly managed for all jobs.

Proposed §26.199(j)(3) would be added to require licensees to document the methods used to conduct their reviews and the results of the reviews. The NRC would use the documentation during site inspections as a means of assuring compliance with the regulations. The methods and results of the reviews would be indicative of a licensee's performance in managing the fatigue of its workers who would be subject to the requirements of this proposed section. Irregularities in the review process may indicate a programmatic weakness that might trigger further inspection activities. The NRC considers the additional recordkeeping burden for documenting this information to be outweighed by the NRC's need to ensure that licensees are complying with the proposed requirements of this section and maintaining effective fatigue management programs.

Proposed §26.199(j)(4) would be added to require licensees to record, trend, and correct, under the licensee's corrective action program, any problems identified in maintaining control of work hours consistent with the specific requirements and performance objectives of Part 26. Accordingly, licensees would be required to maintain the documentation that would be necessary for NRC reviews of licensees' compliance with the proposed work hour controls

within the licensees' existing corrective action programs. The proposed requirement would be in keeping with the existing requirements in 10 CFR Part 50 Appendix B, Criterion XVII, "Quality Assurance Records," and Criterion XVI, "Corrective Action." The NRC would use the documentation during site inspections as a means of assuring compliance with the regulations. The corrective actions and trending would be indicative of a licensee's performance in managing the fatigue of its workers who would be subject to the requirements of this part. Irregularities in the corrective action process may indicate a programmatic weakness that might trigger further inspection activities. The NRC considers the additional recordkeeping burden for documenting this information under the existing corrective action program to be outweighed by the NRC's need to ensure that licensees are complying with the proposed requirements and maintaining effective fatigue management programs.

Section 26.201 Fatigue Assessments

A new §26.201 [Fatigue Assessments] would be added to require licensees to conduct fatigue assessments under several conditions. These conditions, which would be specified in proposed §26.201(a)(1)–(a)(4), would include for cause, after a self-declaration, after an event that would require post-event drug and alcohol testing, and as a followup to returning an individual to work after a self-declaration. The proposed assessments would be necessary to determine whether individuals who are observed to be in a condition creating a reasonable suspicion of impaired individual alertness or have indicated that they are not fit for duty because of fatigue can, in fact, safely and competently perform their duties. Further, in situations where there has been a plant event that would require drug or alcohol testing as specified in proposed §26.31(c), this proposed section would require the licensee to conduct a fatigue assessment in order to determine whether fatigue contributed to the event.

Work hour controls are necessary, but not sufficient, to effectively manage worker fatigue. Worker fatigue, and its effects on worker alertness and performance, can result from many causes in addition to work hours (e.g., stress, sleep disorders, daily living obligations) (Rosa, 1995; Presser, 2000). Further, there are substantial individual differences in the ability to work for extended periods without performance degradation from fatigue (Gander, 1998; Jansen, et al., 2003; Van Dongen, et al., 2004a; Van Dongen, et al., 2004b). The work hours controls of proposed §26.199 would provide only partial assurance that individuals are not fatigued. Therefore, fatigue assessments would be essential.

Appropriately assessing fatigue is also important because workers who are experiencing either acute or cumulative fatigue may not be able to perform their duties safely and competently, as discussed in Section IV. D. There is a large body of research that demonstrates the negative effects of fatigue on individuals' abilities to perform. The literature includes studies comparing the effects of fatigue with those of alcohol intoxication. The effects of both conditions can be expressed in the form of performance decrements. Studies have correlated hours of wakefulness with equivalent blood alcohol concentrations showing that the performance decrements resulting from fatigue are at least as severe as the performance decrements observed when individuals consume the legal limit of alcohol (Dawson and Reid, 1997; Falleti, et al., 2003). At the extreme, workers who have acute fatigue show symptoms that are similar to those of intoxication. Speech is less precise, attention may be lacking, and normal body movements and posture may be absent. Therefore, it is just as important for a worker to be assessed to determine if he or she is unduly impaired from fatigue as it is for the worker to be evaluated to determine whether he or she is impaired from consuming alcohol.

The objective of the assessments required by proposed §26.201(a)(1)–(a)(4) would be for licensees to appropriately address instances of worker fatigue, including those that are not

prevented by the work hour controls, regardless of the number of hours that the subject individual has worked or rested. As discussed with respect to proposed §26.201(c), these assessments would provide the basis for subsequent management actions for fatigue management (e.g., relieving an individual of duties or requiring additional fatigue mitigation actions). Therefore, fatigue assessments are important for effective fatigue management because they provide the basis for any short-term corrective actions that may be necessary to ensure that individuals are able to safely and competently perform their duties, and any long-term corrective actions that may be necessary to address individual or programmatic issues contributing to recurring instances of fatigue.

Proposed §26.201(a)(1) would specify that licensees must perform a fatigue assessment, in addition to any other testing that would be required under proposed §§26.31(c) and 26.77, if a worker is observed to be in a condition of impaired alertness and there is a reasonable suspicion that he or she may not be fit to safely and competently perform his or her duties. The objective of the proposed requirement would be to ensure that fatigue is considered, in addition to drugs or alcohol, as a cause for impaired alertness. As noted in SECY-01-0113, approximately 80 percent of all for-cause FFD tests conducted annually yield negative results for drugs and alcohol. A fatigue assessment would help to determine if fatigue was the cause for the perceived impairment in circumstances where testing does not support drugs or alcohol as the probable cause.

Common indications of impaired alertness include yawning, red eyes, prolonged or excessive blinking, rubbing of the face with the hands, and gross body movements to maintain alertness. Individuals may take substantially longer to complete routine tasks, exhibit difficultly processing written or oral communications, and may become less talkative. At the extreme, workers who are experiencing acute fatigue have symptoms that are similar to those of

intoxication, as discussed with respect to proposed §26.201. Individuals who are fatigued are more likely to complain of illness, pain, or discomfort. In addition to decreased vigor, fatigued individuals may be more irritable, engage in inappropriate humor, exhibit less conservative decision-making, and persevere in using ineffective problem solutions (Horne, 1988; Harrison and Horne, 2000; Dinges, et al. 1997; Pilcher and Huffcutt, 1996; Belenky, et al. 2003; Monk, 2003).

Proposed §26.201(a)(1) would not require licensees to conduct a fatigue assessment if indications of impaired individual alertness are observed during an individual's break period. The NRC considered a comment from the IBEW at a September 14, 2004, public meeting expressing concern with for-cause assessments for work performed outside of the PA. Although whether a worker is inside the PA is not a criterion for being subject to Part 26 requirements, the NRC recognizes that napping is an effective means for reducing worker fatigue. Therefore, proposed §26.201(a)(1) would exclude napping during a break period as a condition for which the proposed provision would require a for-cause fatigue assessment.

Proposed §26.201(a)(1) would also permit licensees to conduct a fatigue assessment, without drug and alcohol testing, if the observed condition is impaired alertness, with no other indication of possible substance abuse. In developing the proposed requirement for for-cause fatigue assessments, the NRC considered stakeholder comments during the public meetings described in Section V. Stakeholders expressed concern that testing for drugs and alcohol, in addition to fatigue, when the only apparent cause of impairment was decreased alertness, would cause stigma, burden, and reluctance to raise FFD concerns that may result in for-cause testing. Accordingly, the proposed requirement would permit licensees to assess only fatigue, if there are no indications of possible substance abuse.

Proposed §26.201(a)(1) would also permit licensees to conduct drug and alcohol testing, without a fatigue assessment, when the licensee has reason to believe that the observed condition is not due to fatigue. The NRC considered stakeholder comments at the public meetings described in Section V that a requirement to perform a fatigue assessment when the licensee has a reasonable basis for believing that the condition is from causes other than fatigue would be an undue burden. In many cases, an observed condition may clearly relate to drugs or alcohol only (such as the smell of alcohol on an individual), and in such cases there would be no benefit from requiring a fatigue assessment.

Proposed §26.201(a)(2) would be added to require licensees to conduct a fatigue assessment if an individual makes a self-declaration that he or she may not be fit to safely and competently perform his or her duties because of fatigue, except if the licensee permits or requires the individual to take a rest break of at least 10 hours. Self-declarations provide assurance that instances of worker fatigue, including those that are not prevented by the work hour controls in proposed §26.199, are appropriately addressed, regardless of the number of hours the individual has worked or rested. Current §26.27(b)(1) requires that "impaired workers, or those whose fitness may be questionable, shall be removed from activities within the scope of this part, and may be returned only after determined to be fit to safely and competently perform activities within the scope of this part." A statement by an individual to his or her supervisor that he or she may not be fit to safely and competently perform his or her duties because of fatigue is an indication that the individual's FFD is questionable, and that an assessment, or a rest break of at least 10 hours, would be necessary before the individual may be returned to duty. Therefore, in circumstances in which an individual requests to be relieved of duties because of fatigue and the individual is relieved of duties for at least 10 hours, the proposed rule would not require the licensee to conduct another fatigue assessment before

permitting the individual to return to duty, consistent with current industry practice. Providing a 10-hour break would be consistent with proposed §26.199(b)(2)(i), which would establish required break times between work periods, and is generally considered sufficient to address most acute fatigue conditions.

As discussed with respect to proposed §26.201(c), a fatigue assessment would provide a basis for a licensee to determine whether the individual is able to safely and competently perform his or her duties and what, if any, subsequent management actions for fatigue management are necessary (e.g., relieving an individual of duties or requiring additional fatigue mitigation actions). As discussed with respect to proposed §26.197(b)(1)(ii), licensees would be required to establish controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit because of fatigue.

In developing the proposed requirement for fatigue assessments of individuals who have self-declared, the NRC considered research concerning subjective assessments of alertness. Self-declarations would generally be based on an individual's subjective evaluation of his or her alertness. Studies have indicated that individuals often misjudge their own fatigue, typically by underestimating their level of fatigue and propensity for uncontrolled sleep episodes. This effect is widely recognized by scientists who study sleep and fatigue. Rosekind, et al. (1997) noted that "An important phenomenon, highly relevant to operational environments, is that there is a discrepancy between subjective reports of sleepiness/alertness and physiological measures. In general, individuals will report higher levels of alertness than indicated by physiological measures." As a consequence, individuals who self-declare would tend to be more impaired than they realize. An exception to this tendency has been noted by Dinges, et al. (1988), who noted that naps can benefit the performance of those experiencing

sleep loss, without that benefit being apparent in subjective measures. Therefore, it is not only important to assess self-declarations as an indicator that an individual may not be able to safely and competently perform his or her duties, but also to consider factors in addition to a self-declaration as part of the fatigue assessment.

Proposed §26.201(a)(2) would also specify that licensees must perform fatigue assessments for self-declarations made to an individual's supervisor. The NRC considered stakeholder comments at public meetings that the proposed requirement should be clear with respect to the behavior that constitutes a self-declaration. For example, stakeholders expressed concern that an individual's off-hand remark to a co-worker that he or she is groggy would be considered a self-declaration under the proposed rule and, therefore, require a fatigue assessment in conditions that could be satisfactorily addressed through less formal processes. The NRC's objective is not to supplant these normal processes for licensee workforce management, but to ensure that formal declarations of fatigue are appropriately evaluated and addressed. Therefore, the proposed requirement would specify that fatigue assessments must be conducted for self-declarations concerning an individual's ability to "safely and competently perform his or her duties" and require that the self-declaration must be made to the individual's supervisor. However, as discussed with respect to proposed §26.201(a)(1), a fatigue assessment must be performed in response to an observed condition of impaired alertness. If, in the preceding example, the "groggy" individual remains on duty and is observed to exhibit impaired alertness, a fatigue assessment would be required "for-cause" in accordance with proposed §26.201(a)(1).

Proposed §26.201(a)(3) would be added to specify that licensees must perform a fatigue assessment after an event that would require drug or alcohol testing, as required in proposed §26.31(c)(3). Proposed §26.31(c)(3)(i)–(c)(3)(iii) would specify the events and

conditions requiring post-event drug and alcohol testing. A fatigue assessment would also be necessary in these circumstances to determine whether worker fatigue contributed to the event and, if so, to identify the need for any corrective actions to prevent similar future events. The assessment would also provide the basis for subsequent management actions for fatigue management, as required by proposed §26.201(c) (e.g., relieving an individual of duties or requiring additional fatigue mitigation actions). Further, the fatigue assessment may provide insights concerning the effectiveness of the licensee's fatigue management program.

Consistent with proposed §26.31(d)(5)(ii), the proposed requirement would specify that licensees may not delay necessary medical treatment in order to conduct a fatigue assessment, if the event involved physical harm to the individual. The NRC considers the immediate medical needs of the individual to be paramount. In these circumstances, it is reasonable to presume that the individual has been removed from duty and consequently the individual's level of fatigue would be irrelevant to the immediate protection of public health and safety or the common defense and security.

Proposed §26.201(a)(4) would be added to require licensees to perform a followup fatigue assessment if an individual is to be returned to work after a break of fewer than 10 hours following a fatigue assessment that was performed for cause or in response to a self-declaration. Although sleep periods of less than 8 hours (e.g., naps) can mitigate some effects of fatigue, such sleep periods are typically insufficient to provide complete recovery from fatigue (McCallum, et al., 2003; Dinges, et al 1997; Totterdell, et al., 1995). As a consequence, the objective of this proposed provision would be to ensure that, in circumstances of sleep periods of less than 8 hours (e.g., if a licensee provides an individual an opportunity for a nap rather than a 10-hour break), the short rest break has provided sufficient rest to mitigate the individual's fatigue, and that the individual is not still groggy from sleep inertia. Sleep inertia is

the grogginess that an individual experiences in the transition from sleep to wakefulness that can temporarily affect an individual's ability to safely and competently perform his or her duties (Bruck and Pisani, 1999; Sallinen, et al., 1998). Further, the assessment would ensure that the individual is capable of performing his or her duties safely and competently during the upcoming work period. It would also provide the information necessary for the licensee to determine whether any controls or conditions must be implemented during the work period (Priest, 2000; Baker, et al., 1990; Sallinen, 1998; Kruger, 2002).

Proposed §26.201(b) would be added to require that either a supervisor or a staff member of the FFD program, who is trained in accordance with the requirements of proposed §§26.29 and 26.197(c), must conduct any fatigue assessment that would be required under proposed §26.201. In accordance with proposed §26.201(c), fatigue assessments would provide the basis for subsequent actions for fatigue management (e.g., relieving an individual of duties or requiring additional fatigue mitigation actions). In addition, the NRC recognizes that fatigue assessments may be used by some licensees as a basis for imposing sanctions on individuals. Therefore, the authority to perform fatigue assessments should be limited to supervisors or staff members of the FFD program. The training required by §§26.29 and 26.197(c) would provide the knowledge and abilities that are essential to a supervisor's or FFD program staff member's ability to make valid assessments in this regard. Among other FFD topics, the proposed training would address: (1) the contributors to worker fatigue and decreased alertness in the workplace; (2) symptoms of worker fatigue; (3) indications and risk factors for common sleep disorders; and (4) the effective use of fatigue countermeasures. Individuals would also be required by proposed §26.29(b) to demonstrate successful completion of the training by passing a comprehensive examination that addresses the KAs.

Proposed §26.201(b) would further require that supervisors or FFD program staff members must perform the fatigue assessment face to face with the subject individual. This proposed requirement would ensure that the individual performing the assessment has the opportunity to (1) observe the subject individual's appearance and behavior to note indications of fatigue (e.g., decreased facial tone, rubbing of eyes, slowed speech); (2) interact with the individual to understand the individual's self-assessment of his or her ability to safely and competently perform his or her duties; and (3) understand any factors in addition to the individual's work schedule that may have contributed to fatigue.

Proposed §26.201(b)(1) would be added to prohibit individuals who observe another individual who is exhibiting indications of impaired alertness from performing the for-cause fatigue assessment of that individual. Without this proposed prohibition, a single supervisor could potentially both observe a worker exhibiting indications of impairment from fatigue and also conduct the for-cause assessment of that worker. In accordance with proposed §26.201(c), fatigue assessments would provide the basis for subsequent management actions for fatigue management. In addition, some licensees may use fatigue assessments as a basis for imposing sanctions on individuals, if, for example, a licensee believes that an individual has been negligent in maintaining his or her FFD. Therefore, in the case of fatigue assessments that would be conducted for cause, the fatigue assessment should be performed by an independent third party to provide reasonable assurance of an objective assessment.

Proposed §26.201(b)(2) would be added to prohibit individuals from performing a post-event fatigue assessment in those circumstances specified in proposed §26.201(b)(2)(i)–(b)(2)(iii), in which a conflict of interest may be present. An individual who has a conflict of interest may not provide an objective assessment of the subject individual's fatigue. The proposed requirement would provide assurance of an objective fatigue assessment by

prohibiting individuals from performing the assessment who were directly responsible for performing the work or assessing the individuals who were involved in the event.

Proposed §26.201(b)(2)(i) would be added to prohibit individuals from performing a post-event fatigue assessment if they performed or directed the work activities during which the event occurred. A supervisor who performed some of the work activities during which the event occurred may benefit from either positive or negative results from a fatigue assessment of another individual, depending on the circumstances. Similarly, a supervisor who directed the work activities of an individual may avoid an adverse action against himself or herself for the actions of a fatigued individual under his or her supervision if the supervisor erroneously assessed the individual as not fatigued. Therefore, the proposed rule would prohibit these individuals from performing fatigue assessments under the specified conditions.

Proposed §26.201(b)(2)(ii) would be added to prohibit individuals from performing a post-event fatigue assessment if they performed, within 24 hours before the event occurred, a fatigue assessment of the individuals who were performing or directing the work activities during which the event occurred. These individuals may have a conflict of interest. For example, if an individual had previously self-declared fatigue, but a fatigue assessment determined he or she was fit to continue work, and an event subsequently occurred that would require the subject individual to be assessed again, then the supervisor who performed the first assessment may avoid adverse action for their previous determination by performing the post-event fatigue assessment and erroneously determining the individual was not fatigued. Therefore, the proposed rule would prohibit these individuals from performing fatigue assessments under the specified conditions.

Proposed §26.201(b)(2)(iii) would be added to prohibit individuals from performing a post-event fatigue assessment if they evaluated or approved a waiver of the limits specified in

proposed §26.199(d)(1) and (d)(2) for any of the individuals who were performing or directing the work activities during which the event occurred, if the event occurred while such individuals were performing work under that waiver. For example, a supervisor who previously assessed an individual such that the individual would be permitted to perform work under a waiver would benefit from an assessment that the individual was not fatigued if an event occurred while the individual was working under the waiver. Therefore, the proposed rule would prohibit these individuals from performing fatigue assessments under the specified conditions.

Proposed §26.201(c) would be added to require that fatigue assessments must provide the information necessary for management decisions and actions in response to the circumstance that initiated the assessment. This information would be necessary to determine the subject individual's ability to safely and competently perform his or her duties, as well as any controls or conditions that must be implemented. Proposed §26.201(c) would provide assurance that fatigue assessments include sufficient and appropriate information to support a valid assessment of the individual relative to fatigue and therefore an appropriate basis for management decisions and actions. The criteria listed in proposed §26.201(c)(1)(i)–(c)(1)(iii) would specify the minimum considerations for fatigue assessments.

In determining the scope of the proposed assessments, the NRC considered the need for licensees to be able to focus the assessment on information that would be readily available and verifiable. Proposed §26.201(c) would require the assessment to address the three work schedule factors that are generally considered to be the largest determinants of worker fatigue (Akerstedt, 2003, 2004; McCallum, et al., 2003; Mallis, et al., 2002; Folkard and Monk, 1980; Rosa, 1995; Rosa, et al., 1996), as follows:

Proposed §26.201(c)(1)(i) would be added to specify the first criterion that fatigue assessments would address, which is acute fatigue. Acute fatigue directly affects an

individual's ability to safely and competently perform his or her duties, as discussed in Section IV. D. Licensees could assess the potential for acute fatigue by estimating, at a minimum, the total number of continuous hours the individual has been awake, as well as considering other individual factors or information provided by the individual (such as his or her ability to obtain rest during break periods).

Proposed §26.201(c)(1)(ii) would be added to specify the second criterion that fatigue assessments would address, which is cumulative fatigue. Cumulative fatigue also directly affects an individual's ability to safely and competently perform his or her duties, as discussed in Section IV. D. Licensees could assess the potential for cumulative fatigue by reviewing, at a minimum: (1) the individual's work schedule during the past 14 days to assess whether the individual had adequate opportunity to obtain sufficient rest, considering the length and sequencing of break periods; (2) whether the available sleep periods occurred during the night or at other times when sleep quality may be degraded; (3) the potential for transitions between shifts (e.g., from days to nights) to have interfered with the ability of the individual to obtain adequate rest; as well as (4) other individual factors or information provided by the individual (such as any personal issues that impact his or her ability to obtain adequate sleep). For cumulative fatigue, the sleep medicine scientific establishment uses the concept of a "sleep debt," which is analogous to a bank account becoming overdrawn, and is a measure of how much an individual's sleep is being cumulatively reduced from his or her everyday sleep need. Many individuals build up a slight sleep debt during the working week, dissipating it by "catch-up" sleep on weekends (National Sleep Foundation, 2000; Monk, et al., 2001). Therefore, in evaluating cumulative fatigue, how much of a "sleep debt" the worker had accrued in the preceding week needs to be evaluated. Dinges and colleagues (1997) noted a five- to seven-fold increase in the percentage of subjects noting a significant "illness, infection, pain,

discomfort, worry or problem" in their daily logs as they progressed from baseline through the seven nights of restricted sleep. In addition to the expected decrements in vigor over the restricted sleep days, subjects' ratings indicated increases in confusion-bewilderment, tension-anxiety, and total mood disturbance.

Symptoms of cumulative fatigue are in some ways similar to those of acute fatigue, but in other ways quite different. The term, "burnout," has been used to describe workers experiencing cumulative fatigue. Similar to burnout from other sources, burnout from cumulative fatigue is often characterized by a lack of initiative and/or creativity, with the individual just "going through the motions like a zombie" without being actively engaged or involved in the job he or she is being asked to perform. Harrison and Horne (2000) advanced the view that the more creative thought processes are those most likely to be impaired by the individual receiving insufficient amounts of the "core" sleep needed for cognitive restitution. They note "[sleep deprivation] presents particular difficulties for decision-making involving the unexpected, innovation, revising plans, competing distraction and effective communication."

Proposed §26.201(c)(1)(iii) would be added to specify the third criterion that fatigue assessments would be required to address, which is circadian variations in alertness and performance. The impact of such variations on an individual's ability to safely and competently perform his or her duties is discussed in Section IV. D. Licensees could assess the potential for circadian degradations in alertness and performance by considering the time of day or night during which the work was or would be performed and whether the time period coincides with a circadian trough in the individual's level of alertness.

Proposed §26.201(c)(2) would be added to require that individuals must provide complete and accurate information that may be required by the licensee to address the factors listed in proposed §26.20(c)(1) (i.e., acute fatigue, cumulative fatigue, and circadian variations

in alertness and performance). Although work hours are an important determinant of worker fatigue, there are many other factors that can affect worker fatigue, not all of which may be readily apparent to a licensee. As a consequence, effective assessment and management of fatigue is a shared responsibility of individuals and licensees, and depends upon complete and accurate communication between the individual and the licensee concerning matters that may influence an individual's level of fatigue. For example, licensees may be able to estimate the total number of continuous hours that an individual has been awake through review of the individual's work schedule and assumptions regarding typical waking times for individuals on that schedule. However, individuals can provide information to better approximate the number of hours they have been continuously awake and facilitate a more accurate assessment of acute fatigue. Additionally, individuals may be able to provide information about their general level of work and non-work-related activities, and opportunities for rest during the period addressed in the fatigue assessment.

Licensees can practically assess the potential for cumulative fatigue by reviewing the individual's work schedule during the past 14 days to identify schedule features that typically influence whether an individual has had adequate opportunity to obtain sufficient rest. However, there are substantial individual differences in the ability to adapt to various schedules (Monk and Folkard, 1985). Therefore, individuals can provide general information related to the quality and quantity of sleep that they actually obtained during this period, which would substantively improve the licensee's assessment of the potential for cumulative fatigue.

Licensees can practically assess the potential for circadian degradations in alertness and performance by considering the time of day or night during which the work has been or would be performed and whether the time period would coincide with a circadian trough in alertness for the individual. However, individuals differ in the extent and rate at which they

adapt to work during periods in which they would otherwise be asleep (Folkard and Tucker, 2003; Carrier and Monk, 2000) and can provide information (e.g., the timing of their sleep periods) that can better inform a licensee's assessment of the potential for circadian degradations in alertness.

Proposed §26.201(c)(2) would also limit licensees' inquiries to obtaining from the subject individual only the information that is necessary to assess the factors listed in proposed §26.201(c)(1). The fatigue assessment should provide a valid basis for licensee decisions and actions for fatigue management without undue invasion of an individual's privacy. For example, inquiries limited to the amount, quality, and timing of sleep, and general activity level of the individual can support an accurate fatigue assessment without the need for an individual to divulge personal details about the reasons for missed sleep or abnormal timings for sleep. Consistent with proposed §26.37 [Protection of information], licensees would be required to keep any information from the individual's self-disclosures confidential.

Proposed §26.201(d) would be added to prohibit licensees from concluding that fatigue had not or will not degrade the individual's ability to safely and competently perform his or her duties solely on the basis that the individual's work hours have not exceeded any of the limits specified in proposed §26.199(d)(1) or that the individual has had the minimum rest breaks required in proposed §26.199(d)(2). The individual work hour controls of proposed §26.199(d)(1) and (d)(2) would be intended to provide reasonable measures to prevent fatigue due to excessive work hours. However, the proposed controls address only work hours and the length of rest breaks, and as a consequence, compliance with these controls may not prevent an individual from experiencing fatigue from one or more of the many other factors that can cause fatigue, some of which may not be readily apparent to an employer. Workload and the type of work an individual performs, home stresses, sleep disorders, and differences in an

individual's ability to work extended hours or adapt to certain schedules can all substantively affect worker fatigue (Rosa, 1995; Totterdell, et al., 1995; Knauth and Hornberger,2003). Although the NRC considered the findings from studies of work hours and worker fatigue in developing the proposed maximum work hours and minimum rest requirements of proposed §26.199(d)(1) and (d)(2), it is neither practical nor possible to establish limits that would prevent fatigue for all individuals. Therefore, the proposed rule would require licensees to consider factors in addition to work hours and rest breaks when determining whether an individual is fit to safely and competently perform duties.

Proposed §26.201(e) would be added to require that, following a fatigue assessment, the licensee must decide whether the individual may perform job duties without a rest break, and, if so, whether controls and conditions must be established under which the individual may perform those duties. Controls and conditions may be necessary to ensure that the duties are performed in a safe and competent manner. Examples of controls and conditions would include, but would not be limited to: (1) a rest break; (2) peer review and approval of assigned job tasks; (2) assignment of job tasks that are non-repetitive in nature; (3) assignment of job tasks that are simple in nature; and (4) assignment to job duties that are not important to the protection of public health and safety or common defense and security. Proposed §26.201(e) would also require licensees to ensure that any controls and conditions that have been determined to be necessary to return an individual to duty would be implemented.

Proposed §26.201(f) would be added to require that licensees must document the results of any fatigue assessments that are performed, the circumstances that necessitated the fatigue assessments, and any controls and conditions that were implemented. The proposed documentation would be necessary for NRC inspectors to evaluate the fatigue assessment component of licensees' FFD programs and for the licensee to conduct the reviews required

under proposed §26.199(j) [Reviews]. The information that the proposed rule would require licensees to document would provide indicators of how well a licensee's fatigue mitigation program at a site is performing.

Subpart J – Recordkeeping and Reporting Requirements

Section 26.211 General provisions

Proposed §26.211 [General provisions] would be added to define general requirements related to recordkeeping and reporting under Part 26.

Proposed §26.211(a) would establish a requirement that licensees and other entities who are subject to this part must maintain records and submit certain reports to the NRC, consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule. In addition, the proposed paragraph would require that licensees and other entities retain the records required under the proposed rule for either the periods that are specified in proposed Subpart J or for the life of the facility's license, certificate, or other regulatory approval, if no records retention requirement is specified. This general records retention requirement is a standard administrative provision that is used in all other parts of 10 CFR that contain substantive requirements applicable to licensees and applicants, such as 10 CFR 50.71(c), and would be added for clarity in the language of the rule.

Proposed §26.211(b) would be added to permit records to be stored and archived electronically if the method used to create the electronic records: (1) provides an accurate representation of the original records; (2) prevents the alteration of any archived information and/or data once it has been committed to storage; and (3) allows easy retrieval and re-creation of the original records. The proposed paragraph would be added to recognize that most

records are now stored electronically and must be protected to ensure the integrity of the data. The proposed requirements would be consistent with related requirements in the access authorization orders issued to nuclear power plant licensees dated January 7, 2003, and would, therefore, meet Goal 4 of this rulemaking, which is to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Section 26.213 Recordkeeping requirements for licensees and other entities

Proposed §26.213 [Recordkeeping requirements for licensees and other entities] would amend current §26.71 [Recordkeeping requirements]. Current §26.71(d), which establishes requirements for FFD program performance reports, would be retained in a separate section that would focus only on those reports in proposed §26.217 [Fitness-for-duty program performance data]. Proposed §26.213 would retain but amend current §26.71(a)–(c) and add other requirements that are interspersed throughout the current rule. These proposed changes would be made to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, by grouping recordkeeping requirements that apply to licensees and other entities in one section.

Proposed §26.213(a) would require licensees and other entities to retain certain records related to authorization decision-making for at least 5 years after an individual's authorization has been terminated or denied, or until the completion of all related legal proceedings, whichever is later. The proposed requirement to retain records until the completion of all related legal proceedings would be added at the suggestion of stakeholders during the public meetings discussed in Section V. The stakeholders noted that some legal proceedings involving records of the type specified in the proposed paragraph have continued longer than

the 5 years that the current rule requires these records to be retained and that adding a requirement to retain the records until all legal proceedings are complete would protect individuals' right to due process under the rule. The proposed change would be consistent with Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Proposed §26.213(a)(1) would amend current §26.71(a), which requires licensees to retain records of the inquiries that licensees conduct in granting unescorted access to an individual for 5 years following the termination of such access authorizations. The proposed paragraph would update the terminology used in the current paragraph for consistency with the revised language used throughout the proposed rule. For example, the proposed paragraph would refer to "self-disclosures," "employment histories," "suitable inquiries," and "granting authorization," but retain the intent of the current paragraph. The proposed changes in terminology would be made for the reasons discussed with respect to proposed §§26.61 [Self-disclosure and employment history] and 26.63 [Suitable inquiry]. In addition, the current cross-reference to §26.27(a) would be updated to cross-reference the related portions of the proposed rule.

Proposed §26.213(a)(2) would amend current §26.71(b), which requires licensees to retain records that are related to confirmed positive test results that have been confirmed by the MRO. The proposed paragraph would revise the current requirement by requiring licensees and other entities to retain records that are related to any violation of the FFD policy, which would include confirmed positive drug and alcohol test results. This proposed change would be made to ensure that licensees and other entities who may be considering granting authorization to an individual who has previously violated any aspect of an FFD policy can obtain these

records for review as part of the authorization decision-making process specified in proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information].

Proposed §26.213(a)(3) would be added to require licensees and other entities to retain records that are related to the granting and termination of an individual's authorization. The proposed paragraph would be necessary to ensure that licensees and other entities who may considering granting authorization to an individual under proposed Subpart C [Granting and Maintaining Authorization] can determine which category of authorization requirements in proposed Subpart C would apply to the individual, based upon the length of time that has elapsed since the individual's last period of authorization was terminated and whether the individual's last period of authorization was terminated favorably. The proposed categories of authorization requirements are discussed in Section IV. C and in this section, with respect to proposed Subpart C.

Proposed §26.213(a)(4) would be added to require licensees and other entities to retain records that are related to any determination of fitness that was conducted under proposed §26.189 [Determination of fitness]. The proposed requirement would be necessary to ensure that licensees and other entities who may be considering granting authorization to an individual who has previously undergone a determination of fitness can obtain these records for review as part of the authorization decision making process specified in proposed §26.69 [Authorization with potentially disqualifying fitness-for-duty information]. In addition, if an individual who is subject to a followup testing and treatment plan transfers to another FFD program, the reviewing official and SAE of the receiving FFD program, which would take responsibility for implementing the testing and treatment plans, would require access to this information.

Proposed §26.213(b)(1) and (b)(2) would require licensees and other entities to retain records related to FFD training, examinations, audits, audit findings, and corrective actions for

at least 3 years, or until the completion of all related legal proceedings, whichever is later. The proposed paragraphs would retain the 3-year recordkeeping requirements of the current rule in §§26.21(b) and 26.22(c) for training records, and §26.80(c) for audit findings and corrective action records.

Proposed §26.213(c) would amend current §26.71(c), which requires licensees to retain records related to any individual who was made ineligible for authorization for 3 years or longer under current §26.27 [Management actions and sanctions to be imposed] until the Commission terminates each license under which the records were created. The proposed paragraph would require licensees and other entities to retain records concerning 5-year and permanent denials of authorization for 40 years or until, upon application, the NRC determines that the records are no longer needed. The proposed paragraph would add the requirement to retain records related to 5-year denials of authorization for consistency with the more stringent sanctions established in proposed §26.75(c), (d), and (e)(2), in which the sanction of a 3-year denial of authorization has been eliminated, as discussed with respect to those proposed paragraphs. The 40-year retention requirement would be based on the longest expected working life of an individual, rather than on the period of the license. The termination of a license by the Commission would not mean that the individuals whose authorization was denied for 5 years or permanently denied under the licensee's FFD program would necessarily leave the industry. Requiring retention of the records pertaining to those individuals would ensure that the records of the 5-year and permanent denials are available, should the individual seek authorization from another licensee or other entity.

Proposed §26.213(d) would replace the recordkeeping requirement in current §26.20 [Written policy and procedures]. The proposed paragraph would require licensees and other entities to retain superseded FFD policies and procedures for at least 5 years or until they

would no longer be needed to respond to a legal challenge. The period of time that superseded materials would be retained would be increased from 3 to 5 years to ensure that the materials are available if subsequent licensees and other entities require the information in making a determination of fitness. The proposed requirement to retain the policy and procedures related to any matter under legal challenge until the matter is resolved would be added to ensure that the materials remain available, should an individual, the NRC, a licensee, or another entity who is subject to this rule require access to them in a legal or regulatory proceeding.

Proposed §26.213(e) would amend the requirement in current §26.23(a) pertaining to the retention of written agreements for the provision of FFD program services. The proposed paragraph would require licensees and other entities to retain the written agreement for the life of the agreement (as in the current rule) or until completion of all legal proceedings related to an FFD violation that involved the services, whichever is later. The proposed requirement to retain the written agreements for any matter under legal challenge until the matter is resolved would be added to ensure that the materials remain available, should an individual, the NRC, a licensee, or another entity who would be subject to the rule require access to them in a legal or regulatory proceeding.

Proposed §26.213(f) would be added to require licensees and other entities to retain records related to the background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under proposed §26.31(b)(1)(ii), for the length of the individual's employment by or contractual relationship with the licensee or other entity, or until the completion of all related legal proceedings, whichever is later. The proposed paragraph would be consistent with the last phrase of current Section 2.6(c) in Appendix A to Part 26, which requires licensee testing facilities to retain personnel files that include "appropriate data to support determinations of honesty and integrity

conducted in accordance with Section 2.3 of this appendix." The proposed period during which these records must be maintained would be based on the NRC's need to have access to the records for inspection purposes and the potential need for the records to remain available should an individual, the NRC, a licensee, or another entity who would be subject to this rule require access to them in a legal or regulatory proceeding. However, the proposed rule would establish a new limit on the period during which the records must be retained in order to reduce the burden associated with storing such records indefinitely.

Proposed §26.213(g) would be added to require licensees and other entities to retain records of the certification of the scientific and technical suitability of any assays and cutoff levels used for drug testing that are not addressed in this part, provided by a qualified forensic toxicologist, as required under proposed §26.31(d)(1)(i) and (d)(3)(iii)(C). The proposed paragraph would require the licensee or other entity to retain these records for the period of time during which the FFD program continues to test for drugs for which testing is not required under this part, uses more stringent cutoff levels than those specified in this part, or until the completion of all related legal proceedings, whichever is later. This proposed requirement would be necessary to ensure the NRC's access to the records for inspection purposes and that the records remain available should an individual, the NRC, a licensee, or another entity who would be subject to this rule require access to them in a legal or regulatory proceeding.

Section 26.215 Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services

A new §26.215 [Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services] would be added to group together in one section the recordkeeping requirements that apply to collection

sites, licensee testing facilities, and HHS-certified laboratories contained in current §§26.20 and 26.71, and, Sections 2.5(f), 2.6 (c), 2.7(a)(1), 2.7(f)(2), 2.7(g)(8), 2.7(n), 2.7(o)(1) and (o)(3), 2.8(e)(4), 2.9(g), and 3.1 in AppendixA to Part 26. The proposed rule would group these requirements in one section to make them easier to locate within the proposed rule, consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.215(a) would retain the requirement in current Section 2.7(n) in Appendix A to Part 26, which mandates that HHS-certified laboratories and licensee testing facilities must maintain documentation of all aspects of the testing process for at least 2 years, and would extend this requirement to collection sites. The proposed rule would include collection sites within this provision because licensee testing facilities and collection sites may not be co-located, as was typically the case when the current rule was first published. The proposed paragraph would retain the provision in current Section 2.7(n) that the 2-year period may be extended upon written notification by the NRC or any licensee or other entity for whom services are being provided. The proposed rule would also add a requirement to retain the documentation until completion of all legal proceedings related to an FFD violation to ensure that the records remain available should an individual, the NRC, a licensee, or another entity who would be subject to this rule require access to them in a legal or regulatory proceeding.

Proposed §26.215(b)(1)–(b)(14) would be added to list in a single paragraph the documents that must be retained by collection sites, licensee testing facilities, and HHS-certified laboratories. Specifically, those documents would include personnel files of individuals who are no longer working at a collection site, licensee testing facility or HHS-certified laboratory, chain-of-custody documents, quality assurance/quality control records, superseded procedures, all test data, test reports, records on performance testing, records on testing errors

or unsatisfactory performance and the investigation and correction of the errors or unsatisfactory performance, performance records on certification inspections, records on preventative maintenance, records on negative test results based on scientific insufficiency, computer-generated data, printed or electronic copies of computer-generated data, records of individuals accessing secured areas in licensee testing facilities and HHS-certified laboratories, and records of EBT maintenance, inspection, and calibration. This listing of records to be retained comes from provisions of the current rule in §26.20 and §26.71(a); and in Appendix A to Part 26, Sections 2.7(a)(1), 2.7(f)(2), 2.7(g)(8), 2.7(n), 2.7(o)(1), 2.7(o)(3), 2.8(e)(4), 2.9(g), and 3.1. The proposed rule would group them together in a single paragraph to make them easier to locate within the rule, consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Section 26.217 Fitness-for-duty program performance data

A new §26.217 [Fitness-for-duty program performance data] would amend the requirements in current §26.71(d) for collecting, compiling, and submitting FFD program performance data to reduce the burden on licensees and other entities and to make the reporting time consistent with the NRC's need for the information. Specifically, the proposed rule would require licensees and other entities to submit program performance data to the NRC every 12 months, rather than every 6 months. The proposed rule would make additional conforming changes to current §26.71 for consistency with other revisions to the rule, as follows:

Proposed §26.217(a) would retain the requirement in current §26.71(d) that each FFD program subject to Part 26 must collect and compile FFD performance data.

Proposed §26.217(b)(1)–(b)(8) would amend the second sentence of current §26.71(d) to specify the FFD program performance data that a licensee or other entity must report, including the random testing rate, the drugs for which is conducted and cutoff levels, workforce populations tested, numbers of tests administered and results, conditions under which the tests were performed, substances identified, number of subversion attempts by type, and summary of management actions. The proposed paragraph is identical to the requirements of the current provision with two exceptions: (1) the current rule does not require reporting the number of subversion attempts by type and (2) the proposed rule would not require a list of events reported during the reporting period.

The proposed rule would add a requirement for licensees and other entities to report the number of subversion attempts by type. This proposed reporting requirement would be necessary to enable the NRC to monitor the ongoing integrity and effectiveness of FFD programs in detecting subversion attempts, consistent with the NRC's heightened concern with this issue, as discussed with respect to proposed §§26.31(d)(3)(i) and 26.75(b). Although this information would be available to NRC inspection personnel at each site, it would be costly and an inefficient use of inspection resources for inspectors to aggregate and report it annually. Under the current rule, licensees typically report subversion attempts they have detected under the requirement to summarize "events reported" in current §26.71(d). Therefore, the NRC expects that the proposed reporting requirement would impose a minimal additional burden.

The proposed rule would eliminate the current requirement to include the number of events reported to the NRC during the reporting period. The current reporting requirement would be eliminated because the NRC has access to this information through other avenues and reporting it twice would be unnecessary.

Proposed §26.217(c) would amend the portions of current §26.71(d) that require licensees and other entities to analyze the FFD program performance data semi-annually. The proposed paragraph would require licensees and other entities to analyze FFD program performance data annually, rather than semi-annually, and retain the requirement that actions must be taken to correct program weaknesses. NRC experience in reviewing FFD program performance reports since the rule was first promulgated has shown that reporting twice per year is unnecessary to ensure the continuing effectiveness of FFD programs. Therefore, the proposed rule would relax the semi-annual analysis and reporting requirement. Further, the proposed paragraph would require licensees and other entities to retain for 3 years records of the data, analysis, and corrective actions taken, which is the same as the current requirement in §26.71(d). However, the proposed rule would add a requirement to retain the documentation until completion of any legal proceedings related to an FFD violation to ensure that the records remain available should an individual, the NRC, a licensee, or another entity who would be subject to this rule require access to them in a legal or regulatory proceeding.

Proposed §26.217(d) would retain the last sentence of current §26.71(d), which requires that any licensee who temporarily suspends an individual's authorization or takes administrative actions on the basis of a non-negative initial test result for marijuana or cocaine [under the provisions of current §26.24(d)] must report the results in the annual summary by processing stage (i.e., initial testing at the licensee testing facility, testing at the HHS-certified laboratory, MRO determination). The proposed paragraph would continue to require that the report must include the number of administrative actions taken against individuals for the reporting period. However, the term, "temporarily suspend," would be eliminated from the proposed paragraph and replaced with the term, "administratively withdraw authorization," in response to stakeholder requests at the public meetings discussed in Section V. The stakeholders noted that an

individual is either authorized to perform job duties under Part 26 or not, and that the concept of suspending an individual's authorization is conceptually inconsistent. The NRC concurred with this observation and, therefore, eliminated the inaccurate phrase from the proposed rule.

Proposed §26.217(e) would amend portions of current §26.71(d) to require licensees and other entities to submit the annual summary to the NRC by March 1 of the following year, rather than the current requirement of a semi-annual summary to be reported within 60 days of the end of each 6-month reporting period. This proposed change would be made for consistency with the revised requirement to submit the report semi-annually in proposed §26.217(c), as discussed with respect to that paragraph.

Proposed §26.217(f) would retain the requirement in current §26.71(d) that program performance data may be submitted in a consolidated report as long as the data are reported separately for each site.

Proposed §26.217(g) would introduce a new requirement that C/Vs who maintain an approved drug and alcohol testing program must submit to the NRC the same program performance data that would be required from licensees and other entities who would be subject to the proposed rule, either directly or via the licensee or other entity to whom the C/V provides services, ensuring that duplicate reports are not provided to the NRC. This proposed requirement is needed because the proposed rule would apply directly to C/Vs who maintain licensee-approved programs, rather than applying only to licensees under the current rule, as discussed with respect to proposed §26.3(d).

Section 26.219 Reporting requirements

A new §26.219 [Reporting requirements] would replace current §26.73 [Reporting requirements] and combine them with current Section 2.8(e)(4), (e)(5), and (e)(6) in Appendix A to Part 26. The proposed section would group into one section reporting requirements that are interspersed throughout the current rule to meet Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule.

Proposed §26.219(a) [Required reports] would be added to introduce the proposed section, consistent with Goal 6 of this rulemaking, which is to improve clarity in the organization and language of the rule, by specifying the categories of significant events that licensees and other entities would report to the NRC (i.e., significant violations of the FFD policy, significant FFD program failures, and errors in drug and alcohol testing). The second sentence of the proposed paragraph would retain the requirement in current §26.73(c) that significant events must be reported under this section, rather than under the provisions of 10 CFR 73.71.

Proposed §26.219(b) [Significant FFD policy violations or programmatic failures] would reorganize and amend current §26.73(a)(1), (a)(2), and (b). Proposed §26.219(b) would retain the requirement in current §26.73(b) that notifications of events must be made to the NRC Operations Center within 24 hours of their discovery, but the proposed rule would present this requirement at the beginning of the paragraph to clarify that it applies to all of the events that are listed in the proposed paragraph.

Proposed §26.219(b)(1) would amend current §26.73(a)(1), which requires licensees to report the sale, use, or possession of illegal drugs within a protected area. The proposed paragraph would add a requirement for licensees and other entities also to report the consumption or presence of alcohol in a protected area. This proposed change would be made for consistency with the NRC's increased concern with the adverse effects of alcohol abuse on

safe performance, as discussed with respect to proposed §26.75(e). The proposed change would also be consistent with the revised performance objective in proposed §26.23(d), which is to provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol, as discussed with respect to that paragraph. The consumption or presence of alcohol in a protected area would constitute a significant programmatic failure in achieving this performance objective.

Proposed §26.219(b)(2) would amend current §26.73(a)(2), which requires licensees to report any acts by licensed operators and supervisory personnel involving the sale, use, or possession of a controlled substance; resulting in confirmed positive tests on such persons; involving consumption of alcohol within the protected area; or resulting in a determination of unfitness for scheduled work due to the consumption of alcohol. The proposed rule would expand the current reporting requirement to include SSNM transporter personnel and FFD program personnel. The proposed change would be made to ensure that the NRC is informed of events involving these individuals because of the important roles they play in assuring public health and safety and the common defense and security, in the former case, and the integrity of the FFD program, in the latter.

Proposed §26.219(b)(2)(i) would retain current §26.73(a)(2)(i), which requires licensees and other entities to report any acts by the subject individuals that involve the use, sale, or possession of a controlled substance.

Proposed §26.219(b)(2)(ii) would combine and amend current §26.73(a)(2)(ii) and (a)(2)(iv), which require licensees and other entities to report any confirmed positive tests on such persons and any acts by the subject individuals that result in a determination of unfitness for scheduled work due to the consumption of alcohol, respectively. The proposed paragraph would amend the current requirements by requiring licensees and other entities to report any

acts by the subject individuals that result in a determination that the individual has violated the licensee's or other entity's FFD policy (including subversion as defined in proposed §26.5 [Definitions]). This proposed change would be made for consistency with two other changes to the proposed rule: (1) the addition of validity testing requirements to the proposed rule, as discussed with respect to proposed §26.31(d)(3)(i), and (2) the new requirements in proposed Subpart D [Management actions and sanctions] to impose the same sanctions for confirmed positive alcohol test results as those required for confirmed positive drug test results, as discussed with respect to proposed §26.75(e). Therefore, the proposed rule would require licensees and other entities to report confirmed non-negative validity test results, any other acts to subvert or attempt to subvert the testing process, and confirmed positive alcohol test results for these individuals.

Proposed §26.219(b)(2)(iii) would amend current §26.73(a)(2)(iii), which requires licensees and other entities to report any events involving the consumption of alcohol within the protected area by the subject individuals, by adding the requirement to report any acts involving the consumption of alcohol while performing the job duties that require these individuals to be subject to this part. This proposed change would be made for consistency with the proposed addition of SSNM transporters and FFD program personnel to this paragraph, as discussed with respect to proposed §26.219(b)(2), because transporter and FFD program personnel typically do not work within a protected area. However, the NRC maintains an interest in the consumption of alcohol by the individuals listed in proposed §26.219(b)(2) while they are performing the duties that require them to be subject to this part at any location.

Proposed §26.219(b)(3) would be added to establish a new requirement for licensees and other entities to report any intentional act that casts doubt on the integrity of the FFD program. Because of the wide array of possible intentional acts that could cast doubt on the

integrity of the FFD program and would be of concern to the NRC, the proposed rule would not specify the acts that licensees and other entities must report. However, such intentional acts may include, but would not be limited to: (1) notifying individuals, outside of the FFD program's normal notification procedures, that they will be selected for random or followup testing on a particular date or at a specific time so that the individuals have sufficient time available to attempt to mask drug use by, for example, obtaining a substitute urine specimen or an adulterant, drinking large amounts of liquid in order to provide a dilute urine specimen, or leaving the site to avoid testing; (2) attempting to divert or tamper with urine specimens that are being prepared for transfer to a licensee testing facility or HHS-certified laboratory by stealing the specimens, substituting specimens in the package, or altering the specimens' custody-and-control documentation; (3) attempting to tamper with testing devices and instruments so that they provide false negative test results; (4) collusion by collection site personnel, an MRO, or MRO staff with an individual who is subject to testing to alter the individual's test results; and (5) attempts by information technology personnel to alter the software that is used by the FFD program to randomly select individuals for testing to ensure that specific individuals are not selected. The intentional acts that the proposed rule would require licensees and other entities to report could involve any aspect of the operations of the FFD program and the testing process.

The proposed rule would add this new reporting requirement because of other changes to the proposed rule that would permit licensees and other entities to rely on other Part 26 programs to a much greater extent than currently. The proposed rule would permit licensees and other entities to rely on testing performed by another Part 26 program, FFD training, other programs' suitable inquiries and determinations of fitness, and audits. Therefore, intentional acts that cast doubt on the integrity of one FFD program may also indirectly affect the integrity

and effectiveness of other FFD programs. The NRC would require reporting of these acts in order to monitor their impacts and ensure that other FFD programs that may be affected are informed of the problem so that they may take corrective actions, if necessary.

Proposed §26.219(b)(4) would be added to require licensees and other entities to report any programmatic failure, degradation, or discovered vulnerability of an FFD program that may permit undetected drug or alcohol use or abuse by individuals within a protected area, or by individuals who are assigned to perform job duties that require them to be subject to this part. In Item 10.1 of NUREG–1385, the NRC emphasized that the NRC expects licensees to exercise prudent judgment in determining whether unusual situations should be reported and that the significant events the licensees must report are 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 proposed rule would add §26.219(b)(4) to clarify that significant events and programmatic failures are not limited to those listed in proposed §26.219(b), but would include any programmatic failures or weaknesses that potentially could permit substance abuse to be undetected.

Proposed §26.219(c) [Drug and alcohol testing errors] would reorganize and amend current requirements for reporting errors in drug and alcohol testing for organizational clarity. The proposed rule would retain the current requirements for licensees and other entities to investigate and take corrective actions for drug and alcohol testing errors in proposed §§26.137(f) and 26.167(g) for licensee testing facilities and HHS-certified laboratories, respectively, but would move the reporting requirements to this proposed paragraph.

Proposed §26.219(c)(1) would update the portion of current Section 2.8(e)(4) in Appendix A to Part 26 that mandates that licensees and other entities must report within 30 days of completing an investigation of any testing errors or unsatisfactory performance in blind performance testing at either a licensee testing facility or an HHS-certified laboratory. The proposed paragraph would amend the current requirement by specifying that the report of the incident must include a description of the corrective actions taken or planned. Although licensees and other entities have consistently included a description of corrective actions in such reports, the proposed rule would add this as a requirement to clarify the NRC's intent in the language of the rule.

In addition, the proposed paragraph would add cross-references to other sections of the proposed rule that define processes that may also result in the identification of errors, including the reviews required under proposed §26.39 [Review process for fitness-for-duty violations] and proposed §26.185 [Determining a fitness-for-duty policy violation]. The NRC intended, in the original rule, that testing or process errors discovered in any part of the program, including these review processes, would 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. Therefore, this proposed change would be made to clarify that the requirement to investigate, correct, and report errors would not be limited only to errors identified through blind performance testing in licensee testing facilities and HHS-certified laboratories but also would apply to errors identified through any means.

Proposed §26.219(c)(2) would amend the portion of current Section 2.8(e)(5) in Appendix A to Part 26 that requires licensees to promptly notify the NRC if a false positive error occurs on a blind performance test sample. The proposed paragraph would replace the current

requirement that the report must be made “promptly” with a requirement to report the false positive error within 24 hours of the discovery. This proposed change would be made as a result of the public meetings discussed in Section V, during which the stakeholders noted that “promptly” is vague. Therefore, the proposed rule would clarify the current requirement by establishing a 24-hour time limit for the notification to meet Goal 6 of this rulemaking, which is to improve clarity in the language of the rule.

The proposed rule would establish a 24-hour time limit because false positive test results would cause licensees and other entities to impose sanctions on individuals who have not, in fact, abused drugs. The HHS views false positive test results very seriously and may de-certify a laboratory as a result. The 24-hour time limit would be necessary to ensure that the NRC can quickly notify the HHS of the problem so that the HHS may initiate the applicable steps required under the HHS Guidelines for such circumstances. In addition, the NRC may use the information to inform other licensees and entities who rely on the same HHS-certified laboratory of the problem, so that they may determine whether to require the laboratory or a second laboratory to retest any specimens they have submitted.

Proposed §26.219(c)(3) would be added to require licensees and other entities to report, within 24 hours of the discovery, any false negative errors identified through quality assurance checks of validity screening devices, if the licensee or other entity uses these devices for validity testing at a licensee testing facility. The proposed reporting requirement would be necessary to ensure that the NRC is aware of any device failures, so that other Part 26 programs that rely on the devices may be informed of the error and stop using them until the cause of the error is identified and the problem is resolved. Continued use of unreliable devices may permit attempts to subvert the testing process to go undetected with the result that

individuals who have engaged in a subversion attempt may be granted or allowed to maintain authorization.

The proposed rule would not require licensees and other entities to report false positive errors identified through quality assurance checks of validity screening devices for two reasons. First, other provisions of the proposed rule would prohibit licensees and other entities from taking management actions or imposing sanctions on individuals on the basis of validity screening test results, as discussed with respect to proposed §26.75(h). Second, donors would be protected from adverse consequences of false positive errors because any specimen that yields a non-negative validity screening test result would be forwarded to an HHS-certified laboratory for initial and confirmatory testing, if required, before a licensee or other entity would be permitted to act, as discussed with respect to proposed §26.137(c). Therefore, reporting of false positive errors would be unnecessary to protect the interests of either donors or the public.

Proposed §26.219(d) [Indicators of programmatic weaknesses] would be added to require licensees and other entities to document, trend, and correct non-reportable FFD issues that identify programmatic weaknesses under the licensee's or other entity's corrective action program. The proposed rule would add this requirement because some licensees have not documented, trended, or corrected programmatic weaknesses, while others have created separate systems, with the result that corrective actions for FFD program weaknesses have not been timely or effective. Therefore, the proposed rule would add these requirements for consistency with Criterion XVI in Appendix B to 10 CFR Part 50 to FFD programs and to meet Goal 3 of this rulemaking, which is to improve the effectiveness and efficiency of FFD programs.

The proposed paragraph would also require licensees and other entities to document, trend, and correct any programmatic weaknesses in a manner that protects individuals' privacy.

For example, the proposed paragraph would prohibit licensees and other entities from documenting a single non-negative drug test result in the corrective action program, because such documentation, along with other cues in the work environment, would permit any individual who has access to the corrective action system easily to identify the donor. However, under the proposed rule, the NRC would expect licensees and other entities to document, trend, analyze, and take corrective actions for an increase in the rate of confirmed non-negative test results in the aggregate, if the licensee or other entity determines that the increasing trend indicates programmatic weaknesses rather than improved effectiveness of the FFD program. The proposed requirement to protect individuals' privacy within the corrective action program would be added to meet Goal 7 of this rulemaking, which is to protect the privacy and due process rights of individuals who are subject to Part 26.

Subpart K – Inspections, Violations, and Penalties

A new Subpart K [Inspections, Violations, and Penalties] would be added to the proposed rule to combine into one subpart current §§26.70 [Inspections], 26.90 [Violations] and 26.91 [Criminal penalties]. Proposed §26.221 [Inspections] would retain the requirements in current §26.70. Proposed §26.223 [Violations] would retain the requirements in current §26.90 [Violations]. Proposed §26.225 [Criminal penalties] would retain the requirements in current §26.91 [Criminal penalties].

Appendix A would be deleted in its entirety.

VII. Issues for Public Comment

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

1. Proposed §26.75(b) in Subpart D would increase the sanctions for certain testing-related actions by requiring that: "Any act or attempted act to subvert the testing process, including refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen, for any test required under this part must result in permanent denial of authorization." The NRC requests comments regarding this proposed change.

2. Proposed §26.119 [Determining "shy" bladder] would establish a process for determining whether there is a medical reason that a donor is unable to provide a urine specimen of at least 30 mL. The NRC added this proposed section in response to stakeholder requests and adapted the process from the DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR 40.197). The DOT Procedures also include processes for determining whether there is a medical reason that a donor is unable to provide a specimen of oral fluids (49 CFR 40.263) or a breath specimen (49 CFR 40.265) of sufficient quantity to support alcohol testing. The NRC invites comments on whether the NRC should consider incorporating these processes for insufficient oral fluids and breath specimens in Part 26.

3. Proposed §26.31(d)(3)(iii)(C) would permit licensees and other entities to specify more stringent cutoff levels for the panel of drugs for which testing is required under this part without informing the NRC within 60 days and without obtaining the written approval of the NRC. Proposed §26.31(d)(1)(i)(D) and (d)(1)(ii) would also permit licensees and other entities to test for drugs and drug metabolites in addition to those specified in proposed §26.31(d)(1) without informing or obtaining the written approval of the NRC. However, the proposed

paragraphs would require that the scientific and technical suitability of the more stringent cutoff levels and of the assays and cutoff levels used to test for additional drugs or drug metabolites must be evaluated and certified, in writing, by a qualified, independent forensic toxicologist. Certification by a forensic toxicologist would not be required in three circumstances: (1) if the HHS issues more stringent cutoff levels in the HHS Guidelines and the licensee or other entity adopts the revised HHS cutoffs; (2) if the HHS Guidelines are revised to authorize use of the assay in testing for the additional drug or drug metabolites and the licensee or other entity uses the cutoff levels established in the HHS Guidelines for the drug or drug metabolites; and (3) if the licensee or other entity received written approval from the NRC for the lower cutoff levels and/or for testing for the additional drugs or drug metabolites, under current Section 1.1(2) in Appendix A to Part 26. The proposed paragraphs differ from the current requirement in Section 1.1(2) of Appendix A to Part 26. The NRC requests comments regarding these proposed changes.

4. Proposed §§26.133 and 26.163 would raise the cutoff levels for initial and confirmatory tests for opiates from 300 nanograms (ng) per milliliter (mL) to 2,000 ng/mL. The proposed rule would also require testing for 6-acetylmorphine (6-AM), a metabolite that comes only from heroin, using a 10 ng/mL confirmatory cutoff level for specimens that tested positive on the initial test. The proposed cutoff levels and new test would be consistent with those used by HHS and DOT, and would reduce the number of specimens in Part 26 programs that test positive for opiates at an HHS-certified laboratory but are subsequently determined to be negative by the MRO after consultation with the donor. The NRC invites comment on these proposed changes.

5. In proposed §§26.131, 26.137, 26.161, and 26.167, the NRC would add new requirements for validity testing of urine specimens to detect specimens that may have been

adulterated, substituted, or diluted. The new requirements are adapted from practices the HHS published in the Federal Register on April 13, 2004 (69 FR 19643) as a final rule. The NRC invites public comment on the following issues related to the proposed validity testing requirements.

a. Proposed §26.137 would establish quality assurance and quality control requirements for conducting validity and drug tests of urine specimens. The NRC seeks input regarding any technical and methodological barriers to implementing these requirements at licensee testing facilities.

b. Proposed §§26.161(d) and 26.185(h) would establish criteria and procedures for determining whether a specimen has been substituted. A specimen would be reported by the HHS-certified laboratory to the MRO as substituted if it has a creatinine concentration of less than 2 mg/dL and specific gravity of less than or equal to 1.0010, or equal to or greater than 1.0200. For the HHS-certified laboratory to report a specimen as substituted, results in these ranges would be necessary on both the initial and confirmatory creatinine and specific gravity tests on two separate aliquots of the specimen. The NRC invites comments on the proposed provisions.

6. Proposed §26.183(a) requires that "The MRO shall be knowledgeable of this part and of the FFD policies of the licensees and other entities for whom the MRO provides services." The NRC invites comments on whether Part 26 should establish specific training requirements for the MRO related to this part and the licensee's or other entity's programs for which the MRO provides services.

7. The NRC is considering incorporating future changes to the draft HHS Guidelines that were published as a proposed rule for public comment in the Federal Register on April 13, 2004 (69 FR 19672) relating to the permission in this proposed Part 26 rule for

licensees and other entities to use non-instrumented validity tests to determine whether a urine specimen appears to be adulterated, diluted, or substituted and requires further testing at an HHS-certified laboratory. Proposed Part 26 would permit licensees and other entities to use these devices for validity screening tests, in lieu of the instrumented validity testing required in the April 13, 2004, final version of the HHS Guidelines. Should any changes be made to those draft HHS Guidelines between issuing this proposed rule and issuing the final 10 CFR Part 26 rule, those changes would be considered for incorporation. Any comments related to the potential incorporation of those changes are of interest.

8. Proposed Subpart I, Managing Fatigue, includes many requirements related to worker fatigue at nuclear power plants. The NRC is especially interested in comments on the following provisions:

a. Proposed §26.199(d)(2)(ii) and (d)(2)(iii) would require licensees to provide individuals who are subject to the proposed work hour limits with at least one 24-hour rest break in any 7-day period and at least one 48-hour rest break in any 14-day period, except during the first 14 days of any outage, as well as certain other circumstances for security force personnel.

b. Proposed §26.199(d)(3) would permit licensees to waive individual work hour limits and rest break requirements only in circumstances in which it is necessary to mitigate or prevent a condition adverse to safety, or to maintain the security of the facility. Proposed §26.197(e)(1) would require licensees to report the number of waivers granted in a year.

c. Proposed §26.199(f) would prohibit job duty groups that are subject to work hour controls from working more than a maximum collective average of 48 hours per person per week, except during the first 8 weeks of any outage, as well as certain other circumstances for security force personnel.

9. Proposed §26.199(a) would require any individual who performs duties within specified job duty groups to be subject to the work hour control provisions in §26.199. Other individuals, beyond those specified within the scope of §26.199(a), might substantially impact the outcome of risk-significant work, such as certain engineers (e.g., Shift Technical Advisors). The NRC requests comment on the inclusion of other individuals in the scope of §26.199(a).

10. The NRC is considering amending 10 CFR 50.109, 70.76, and 76.76 to exclude certain future changes to Part 26 from current backfit requirements. The scope of the exclusions would be limited to only those changes to Part 26 that would be necessary to incorporate relevant revisions to the HHS Guidelines when they are published by HHS as final rules. Examples of changes to the HHS Guidelines that may be incorporated into Part 26 in future rulemakings may include, but would not be limited to (1) adopting changes to the cutoff levels established in the Guidelines; (2) the addition or deletion of drugs and adulterants for which testing would be required; and (3) changes in the specimens, instruments, or assays used in drug and validity testing. The NRC requests comment on excluding such future changes to Part 26 from backfit analysis requirements.

11. Proposed §§26.135(b) and 26.165(a)(4) and (b)(1) would prohibit licensees and other entities, the MRO, and the NRC from initiating testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission. The NRC is considering an alternative approach that would permit a licensee or other entity to initiate testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission only if all of the following conditions are met: (1) the first results from testing the specimen were confirmed as non-negative by the MRO; (2) the donor has requested a review under proposed §26.39 or initiated legal proceedings; and (3) the testing is conducted in accordance with proposed §26.165(c)–(e), as applicable. Under either the proposed

provisions or the alternative approach, the proposed rule would require the licensee or other entity to administratively withdraw the donor's authorization until the results from Bottle B or the retest results are available and to rely only on those results in determining whether the licensee or other entity would be required to take management actions or impose sanctions on the donor. The NRC is seeking an appropriate balance between protecting donors' rights to privacy and due process under the rule and the protection of public health and safety and the common defense and security, and invites public comment on the proposed and alternative approaches.

VIII. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is proposing to amend 10 CFR Part 26 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

IX. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the Federal Register on September 3, 1997 (62 FR 46517), this rule is classified as Compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via a

mechanism that is consistent with the particular State's administrative procedure laws but does not confer regulatory authority on the State.

X. Plain Language

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in these proposed revisions to improve the organization and readability of the existing language of the paragraphs being revised. The NRC requests comments on the proposed rule specifically with respect to the clarity and reflectiveness of the language used. Comments should be sent to the address listed under the ADDRESSES caption of the preamble.

XI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. There are no consensus standards regarding the methods for performing drug and alcohol testing, fatigue assessments, or other aspects of Fitness For Duty Programs, that would apply to the requirements that would be imposed by this rule, with the exception of short-term work hour limits for licensed operators, senior operators, and the shift technical advisor. The NRC notes the inclusion of these limits in a 1988 American Nuclear

Society standard on administrative controls and quality assurance for the operational phase of nuclear power plants, ANSI/ANS-3.2-1998.

The NRC does not believe that this standard is sufficient, as it does not apply to other categories of workers who would be subject to the provisions of this proposed rule, such as maintenance, health physics, chemistry, fire brigade, and security force personnel. Additionally, the standard is insufficient because it does not provide the comprehensive fatigue management approach that this proposed rule would, and is lacking provisions to mitigate long-term fatigue, provide a process for self-declarations of fatigue by workers, and provide for rest breaks.

Further, the standard does not adequately mitigate short-term fatigue, because it does not restrict deviations from the short-term limits to only those unique instances necessary for the safety and security of the plant. The standard only requires that exceptions be minimized and that they be approved by the plant manager or designee. The provisions in the standard are identical to those currently incorporated as requirements in some nuclear power plants' technical specifications. Section IV. D explains that enforcement of the technical specification requirements is complicated by the fact that the language is largely advisory, and key terms have not been defined, with the result that the requirements have been interpreted inconsistently.

For the reasons noted above, the ANS standard cannot be used in lieu of the proposed rule provisions to meet the objective of comprehensive fatigue management.

XII. Finding of No Significant Environmental Impact: Environmental Assessment

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if

adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The basis for this determination reads as follows:

The proposed rule, if adopted, would amend the NRC's requirements for FFD programs which are contained in 10 CFR Part 26 to address the following needs: (1) update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) and other Federal drug and alcohol testing programs (e.g., those required by the U.S. Department of Transportation [DOT]) that impose similar requirements on the private sector; (2) strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management worker fatigue; (3) improve the effectiveness and efficiency of FFD programs; (4) improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003; (5) improve 10 CFR Part 26 by eliminating or modifying unnecessary requirements; (6) improve clarity in the organization and language of the rule; and (7) protect the privacy and due process rights of individuals who are subject to 10 CFR Part 26.

It would also grant, in part, a December 30, 1993, petition for rulemaking (PRM-26-1) from Virginia Electric and Power Company (now Dominion Virginia Power) which requested a relaxation in required audit frequencies and PRM-26-2, dated December 28, 1999, from Barry Quigley, by establishing clear and enforceable requirements concerning the management of worker fatigue. In addition, the proposed rule would continue to apply to all personnel with

unescorted access to the protected area of a nuclear power plant, consistent with the Commission's denial (SRM-SECY-04-0229) of an exemption request by IBEW Local 1245 dated March 13, 1990, and renewed on January 26 and December 6, 1993.

The proposed rule would not significantly increase the probability or consequences of an accident. No changes are being made in the types or quantities of radiological effluents that may be released off site, and there is no significant increase in public or occupational radiation exposure since there is no change to facility operations that could create a new or affect a previously analyzed accident or release path.

With regard to non-radiological impacts, no changes are being made to non-radiological plant effluents and there are no changes in activities that would adversely affect the environment. Therefore, there are no significant non-radiological impacts associated with the proposed action.

The primary alternative to this action would be the no action alternative. The no action alternative would result in continued inconsistencies between FFD and access authorization requirements, continued difficulties in implementation of the regulation due to the current organization of the rule, continued use of less current technologies and advances in testing and a continued lack of a comprehensive fatigue management program. The no action alternative would provide little or no safety, risk, or environmental benefit.

No outside agencies or persons were consulted, or outside sources used or relied upon, in the preparation of this environmental assessment.

The determination of this environmental assessment is that there will be no significant environmental impact from this action. However, the general public should note that the NRC is seeking public participation. Comments on any aspect of the environmental assessment, provided above, may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of this proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

XIII. Paperwork Reduction Act Statement

This proposed rule contains new or amended 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 requirements.

Type of submission, new or revision: New

The title of the information collection: 10 CFR Part 26, "Fitness for Duty Programs."

The form number if applicable: Not applicable.

How often the collection is required

On occasion: Significant FFD policy violations or programmatic failures; drug and alcohol testing errors; indicators of programmatic weaknesses; possible impairment of an NRC employee or NRC contractor;

Annually: FFD program performance data

Who will be required or asked to report:

- Licensees authorized to operate a nuclear power reactor;

- Licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under 10 CFR Part 70;

- Corporations, firms, partnerships, limited liability companies, associations, or other organizations that obtain a certificate of compliance or an approved compliance plan under 10 CFR Part 76, if the entity engages in activities involving formula quantities of SSNM; and

- Contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that licensees and other entities rely upon those C/V FFD programs or program elements to meet the requirements of this part.

An estimate of the number of annual responses: 161

The estimated number of annual respondents: 36 FFD programs (used by 65 nuclear power plants, 3 fuel cycle facilities and 2 C/Vs), of which 31 FFD programs (used by 65 nuclear power plant facilities) are also required to include fatigue management programs with additional reporting and recordkeeping requirements.

An estimate of the total number of hours needed annually to complete the requirement or request: 413,685 hours, including 75,273 hours for one-time program implementation, 24,556 hours annually for reporting (an average of 682 hours per respondent) + 313,854 hours annually for recordkeeping (an average of 8,718 hours per recordkeeper).

Abstract: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for its Fitness for Duty (FFD) programs to completely revise 10 CFR Part 26 to update and clarify the regulations, and also add requirements for fatigue management at nuclear power plants. The proposed rule would ensure that individuals subject to these regulations are trustworthy and reliable, as demonstrated by avoiding substance abuse, and are otherwise fit for duty. The proposed rule would also ensure that workplaces subject to these regulations are free of the presence and effects of illegal drugs and alcohol.

The recordkeeping and reporting requirements in the proposed rule include provisions requiring licensees and other entities to develop and maintain policies and procedures; retain records of training, qualification and authorization of individuals; retain records related to drug and alcohol collections and tests; retain other records related to the collection, testing and review processes; report FFD program performance and significant violations, program failures and testing errors; and retain records related to employee assistance programs. Records and reports are also required under the proposed new fatigue management component of the FFD program.

The recordkeeping and reporting requirements would be mandatory for licensees and other entities subject to the rule. The NRC would use the reports to assess the effectiveness of FFD programs for those subject to the rule, and whether the provisions are implemented as the NRC intends.

The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

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

2. Is the estimate of burden 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?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O1-F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC worldwide Web site: http://www.nrc.gov/public-involve/doc-comment/omb/index.html for 60 days after the signature date of this proposed rule and are also available at the rule forum site, http://ruleforum.llnl.gov.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by (INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER) to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0146), Office of Management and Budget, Washington, DC 20503. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also comment by telephone at (202) 395-3087.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XIV. Regulatory Analysis

The NRC has prepared a draft Regulatory Analysis on this proposed regulation. The draft regulatory analysis was prepared in accordance with the NRC's Regulatory Analysis Guidelines (RA Guidelines), NUREG/BR-0058, Revision 4, dated September 2004. The draft Regulatory Analysis consists of three parts. First, an aggregate analysis of the entire rule was performed. Second, a screening review for disaggregation was performed to identify any individual provisions that could impose costs disproportionate to the benefits attributable to each provision. Finally, a separate analysis of the proposed rule's provisions addressing worker fatigue was performed. A description of each of these three elements is discussed below. The analysis is available as discussed above under the ADDRESSES heading. Single copies may be obtained from the contact listed above under the FOR FURTHER INFORMATION CONTACT heading. The Commission requests public comment on the draft Regulatory Analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

A. Aggregate Analysis

Consistent with the RA Guidelines, an aggregate analysis of the entire rulemaking was performed. The provisions of the rule relating to drug and alcohol testing (and other general FFD program requirements) are estimated to result in net present value savings to industry of $116 million–$183 million (using 7 percent and 3 percent real discount rates), consisting of $2 million in one-time costs and $9 million in annual net savings. The worker fatigue portions of the proposed rule are estimated to cost industry $585 million–$913 million net present value (using the 7 percent and 3 percent real discount rates, respectively), consisting of $19 million in one-time costs and $42 million in annual net costs. The net present value of the entire

proposed rule, including both the worker fatigue and drug and alcohol testing portions, is estimated to be a cost to industry of $469 million - $730 million (using 7 percent and 3 percent real discount rates), which consists of $21 million in one-time costs and $33 million in annual costs. In addition, the proposed rule is estimated to be a cost to the NRC of $615,000–$947,000 net present value (using 7 percent and 3 percent real discount rates), consisting of $30,000 in one-time costs and $45,000 in annual net costs.

The NRC also separately evaluated the improvement in worker performance expected from the impact of selected fatigue management provisions on unplanned reactor scrams, reactor accidents, lost and restricted work cases (injuries), fire mitigation, and security. Those present value savings are estimated to be $103 million–$167 million (using 7 percent and 3 percent real discount rates), and have not been subtracted from the net present value of the entire proposed rule listed above because the NRC considers the costs of the proposed rule to be justified without these quantitative savings, which are only included to illustrate further justification for the rulemaking.

The NRC concludes that the costs of the rule are justified in view of the qualitative benefits evaluated in Section 4.1.2 of the draft Regulatory Analysis. The basic analysis measures the incremental impacts of the proposed rule relative to a baseline that assumes full licensee compliance with existing NRC requirements, including current regulations and any relevant orders or enforcement discretion. The aggregate analysis is contained in Section 4.1 of the draft regulatory analysis.

B. Screening Review for Disaggregation

The regulatory analysis also discusses the screening review for disaggregation performed by the staff. The analysis was performed consistent with Section 4.3.2 of the RA

Guidelines to determine if there are provisions whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could obscure their impact, but also responds to the Commission's direction in SRM-01-0134 dated July 23, 2001, that, "If there is a reasonable indication that a proposed change imposes costs disproportionate to the safety benefit attributable to that change, as part of the final rule package the Commission will perform an analysis of that proposed change in addition to the aggregate analysis of the entire rulemaking to determine whether this proposed change should be aggregated with the other proposed change for the purposes of the backfit analysis. That analysis will need to show that the individual change is integral to achieving the purpose of the rule, has costs that are justified in view of the benefits that would be provided or qualifies for one of the exceptions in 10 CFR §50.109(a)(4)." These results are described in Sections 4.1.4.1 and 4.4.2 of the draft regulatory analysis.

C. Dissaggregation of Worker Fatigue Provisions

Section 4.1.4.2 of the draft Regulatory Analysis summarizes the division of costs and savings of the fatigue management portions of the proposed rule, in comparison with the rest of the rule. The worker fatigue portions of the proposed rule are estimated to cost industry $585 million–$913 million net present value (using the 7 percent and 3 percent real discount rates, respectively), consisting of $19 million in one-time costs and $42 million in annual net costs. The NRC considers fatigue management to be an integral and necessary aspect of FFD. Fatigue currently is considered to be part of FFD under current §26.10(a) and §26.20(a)(2). However, the NRC included a summary of the costs associated with the proposed fatigue management requirements in the aggregate as a courtesy to stakeholders in Section 4.1.4.2 of the draft Regulatory Analysis.

XV. Regulatory Flexibility Act Certification

As required by the Regulatory Flexibility Act, as amended, 5 U.S.C. 605(b), the Commission certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect only licensees authorized to operate nuclear power reactors; licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM); corporations who obtain certificates of compliance or approved compliance plans under Part 76 involving formula quantities of SSNM; combined license holders; holders of manufacturing licenses; holders of construction permits; combined license holders and construction permit applicants with authorization to construct; and contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that licensees and other entities rely upon those C/V FFD programs or program elements to meet the requirements of Part 26. Those above do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act, or the Size Standards established by the Nuclear Regulatory Commission (10 CFR 2.810).

XVI. Backfit Analysis

The proposed rule would constitute backfitting as defined in 10 CFR 50.109(a)(1). The NRC has performed a backfit analysis, as described in §50.109(c) [which applies to power reactors], §70.76(b) [which applies to formula quantity strategic special nuclear material licensees], and §76.76(b) [which applies to gaseous diffusion plants], consistent with the NRC's Regulatory Analysis Guidelines (RA Guidelines) in NUREG/BR-0058, Revision 4, dated September 2004. The Commission requests public comment on the draft Backfit Analysis. The draft Backfit Analysis is included in the draft Regulatory Analysis, which is available as discussed under the ADDRESSES heading. Single copies may be obtained from the contact

listed under the FOR FURTHER INFORMATION CONTACT heading. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

A. Consideration of Fuel Fabrication Facilities and Gaseous Diffusion Plants

The backfit provision of 10 CFR 70.76 applies to currently operational fuel fabrication facilities. These facilities have been considered in the aggregate backfit analysis. The planned mixed-oxide fuel fabrication facility would also be licensed under Part 70, but has not yet submitted a Part 26 program description. Therefore, the consideration of the costs to the mixed-oxide fuel fabrication facility in the regulatory analysis is sufficient for consideration of the impacts to that facility. Although the backfit provision of 10 CFR 76.76 would apply to gaseous diffusion plants, there are no backfit impacts because the gaseous diffusion plants licensed by the NRC are not currently authorized to possess formula quantities of strategic special nuclear material.

B. Aggregate Backfit Analysis

The NRC performed an aggregate backfit analysis of all backfits consistent with Section 4.3.2 of the RA Guidelines. Because the changes associated with the proposed rule are interrelated and deal with a single subject area (FFD), the NRC followed its ordinary practice of assessing the backfitting implications in an aggregate manner, consistent with the RA Guidelines. The aggregate analysis is provided in Section 4.4.1 of the draft Part 26 Regulatory Analysis, which is available as discussed under the ADDRESSES heading. The aggregate analysis also includes a list of all changes that constitute backfits, in Exhibits 4-14 and 4-15 of the draft analysis. Exhibit 4-16 of the draft analysis also includes a list of all changes that were

evaluated for potential cost implications, but were determined to not constitute backfits, as well as a list of the reasons those changes were determined to not constitute backfits. A summary of the results of the aggregate analysis follows.

The NRC determined the backfitting is justified under §50.109(a)(3), §70.76(a)(3) and §76.76(a)(3) because: (1) there is a substantial increase in the overall level of protection afforded for the public health and safety or the common defense and security to be derived from the backfitting; and (2) the costs of implementation and the annual costs are justified in view of this increase. The estimated cost of implementation would be $21 million and the annual net costs would be $42 million, resulting in a net present value cost of $594 million–$927 million (using 7 percent and 3 percent real discount rates, respectively).

In determining that the substantial increase standard is met, the NRC considered safety benefits qualitatively. In this qualitative consideration, the NRC determined that the proposed FFD rule, considered in the aggregate, would constitute a substantial increase in protection to public health and safety by addressing the following six key areas that have been identified as posing recurring and, in some cases, significant problems with respect to the effectiveness, integrity, and efficiency of FFD programs at nuclear facilities.

1. Subversion of the detection/testing process;
2. Regulatory efficiency between 10 CFR Part 26 and other related Federal rules and guidelines;
3. Ineffective/unnecessary FFD requirements;
4. Ambiguous or imprecise regulatory language in 10 CFR Part 26;
5. Technical developments; and
6. FFD program integrity and protection of individual rights.

In addition to the six areas above, the NRC noted in its draft analysis a significant qualitative benefit in the management of worker fatigue for key personnel at nuclear power plants.

C. Screening Review for Disaggregation

The NRC also performed a screening review, consistent with Section 4.3.2 of the RA Guidelines, to determine if there are provisions constituting backfits whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could obscure their impact. The NRC identified 15 proposed backfits with reasonable indications that the costs associated with the proposed backfit may be disproportional to the safety benefit attributable to the change. The NRC determined that all of the 15 proposed backfits were necessary to meet the objectives of the rule. Therefore, the staff did not disaggregate any of those individual provisions and perform a separate backfit analysis for each provision. A detailed discussion of the screening review, including the reasons why each of the 15 proposed backfits were determined to be necessary to meet the objectives of the proposed rule is described in Section 4.4.2 of the draft Regulatory Analysis.

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XVIII. List of Subjects in 10 CFR Part 26

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

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

1. Part 26 is revised in its entirety to read as follows:

PART 26 – FITNESS FOR DUTY PROGRAMS

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

Subpart A – Administrative Provisions

§26.1 Purpose.

This part prescribes requirements and standards for the establishment, implementation, and maintenance of fitness-for-duty (FFD) programs.

§26.3 Scope.

(a) The regulations in this part apply to licensees who are authorized to operate a nuclear power reactor (under §50.57 of this chapter) and holders of a combined license after the Commission has made the finding under §52.103 of this chapter.

(b) The regulations in this part, except those contained in Subpart I, also apply to licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under Part 70 of this chapter.

(c) In addition, the regulations in this part, except those contained in Subpart I, apply to a corporation, firm, partnership, limited liability company, association, or other organization that obtains a certificate of compliance or an approved compliance plan under Part 76 of this chapter, only if the entity elects to engage in activities involving formula quantities of SSNM. When applicable, the requirements apply only to the entity and personnel specified in §26.25(a)(3).

(d) The regulations in this part also apply to contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that licensees and other entities rely upon those C/V FFD programs or program elements to meet the requirements of this part.

(e) Combined license holders (under Part 52 of this chapter) before the Commission has made the finding under §52.103 of this chapter, combined license applicants who have received authorization to construct under §50.10(e)(3), construction permit holders (under Part 50 of this chapter), construction permit applicants who have received authorization to construct under §50.10(e)(3), and holders of manufacturing licenses (under Part 52 of this chapter) shall —

(1) Comply with §§26.23, 26.41, and 26.189;

(2) Implement a drug and alcohol testing program, including random testing; and

(3) Make provisions for employee assistance programs, imposition of sanctions, procedures for the objective and impartial review of authorization decisions, protection of information, and recordkeeping.

(f) The regulations in this part do not apply to either spent fuel storage facility licensees or non-power reactor licensees who possess, use, or transport formula quantities of irradiated SSNM because these materials are exempt from the Category I physical protection requirements set forth in 10 CFR 73.6.

§26.5 Definitions.

Acute fatigue means fatigue from causes (e.g., restricted sleep, sustained wakefulness, task demands) occurring within the past 24 hours.

Adulterated specimen means a urine specimen that contains a substance that is not a normal constituent, or one that contains an endogenous substance at a concentration that is not a normal physiological concentration.

Alertness means the ability to remain awake and sustain attention.

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

Analytical run means the process of testing a group of urine specimens for validity or for the presence of drugs and/or drug metabolites. For the purposes of defining the periods within which performance testing must be conducted by licensee testing facilities and HHS-certified laboratories who continuously process specimens, an analytical run is defined as no more than an 8-hour period. For a facility that analyzes specimens in batches, an analytical run is defined as a group of specimens that are handled and tested together.

Best effort means documented actions that a licensee or other entity who is subject to this part takes to obtain suitable inquiry and employment information in order to determine whether an individual may be authorized to have the types of access or to perform the activities specified in §26.25(a), when the primary source of information refuses or indicates an inability or unwillingness to provide the information within 3 business days of the request and the licensee or other entity relies upon a secondary source to meet the requirement.

Blood alcohol concentration (BAC) means the mass of alcohol in a volume of blood.

Calibrator means a solution of known concentration which is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a test specimen/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a cutoff concentration and/or a calibration curve over a range of interest.

Category IA material means SSNM that is directly usable in the manufacture of a nuclear explosive device, except if the material meets any of the following criteria:

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

(2) The total weight of an encapsulated item of SSNM is such that it cannot be carried inconspicuously by one person (i.e., at least 50 kilograms gross weight); or

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

Chain of custody means procedures to account for the integrity of each specimen or aliquot by tracking its handling and storage from the point of specimen collection to final

disposition of the specimen and its aliquots. “Chain of custody” and “custody and control” are synonymous and may be used interchangeably.

Circadian variation in alertness and performance means the increases and decreases in alertness and cognitive/motor functioning caused by human physiological processes (e.g., body temperature, release of hormones) that vary on an approximately 24-hour cycle.

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

Collector means a person who is trained in the collection procedures of this part, instructs and assists a specimen donor at a collection site, and receives and makes an initial examination of the specimen(s) provided by the donor.

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

Confirmatory drug or alcohol test means a second analytical procedure to identify the presence of alcohol or a specific drug or drug metabolite in a specimen. The purpose of a confirmatory test is to ensure the reliability and accuracy of an initial test result.

Confirmatory validity test means a second test performed on a different aliquot of the original urine specimen to further support a validity test result.

Confirmed test result means a test result that demonstrates that an individual has used drugs or alcohol in violation of the requirements of this part or has attempted to subvert the testing process by submitting an adulterated or substituted urine specimen. For drugs, adulterants, and substituted specimens, a confirmed test result is determined by the Medical Review Officer (MRO), after discussion with the donor subsequent to the MRO’s receipt of a

positive confirmatory drug test result from the HHS-certified laboratory and/or a non-negative confirmatory validity test result from the HHS-certified laboratory for that donor. For alcohol, a confirmed test result is based upon a positive confirmatory alcohol test result from an evidential breath testing device without MRO review of the test result.

Contractor/vendor (C/V) means any company, or any individual not employed by a licensee or other entity who is subject to this part, who is providing work or services to a licensee or other entity subject to this part, either by contract, purchase order, verbal agreement, or other arrangement.

Control means a sample used to monitor the status of an analysis to maintain its performance within predefined limits.

Cumulative fatigue means the increase in fatigue over consecutive sleep-wake periods resulting from inadequate rest.

Cutoff level means the concentration established for designating and reporting a test result as non-negative.

Dilute specimen means a urine specimen with creatinine and specific gravity concentrations that are lower than expected for human urine.

Directing means the exercise of control over a work activity by an individual who is directly involved, capable of making technical decisions, and ultimately responsible for the correct performance of that work activity.

Donor means the individual from whom a specimen is collected.

Employment action means a change in job responsibilities or removal from a job, or the mandated implementation of a plan for substance abuse treatment in order to avoid a change in or removal from a job, because of the individual's use of drugs or alcohol.

Fatigue means the degradation in an individual's cognitive and motor functioning resulting from inadequate rest.

Formula quantity means strategic special nuclear material in any combination in a quantity of 5000 grams or more computed by the formula, grams=(grams contained U-235)+2.5 (grams U-233+grams plutonium). This class of material is sometimes referred to as a Category I quantity of material.

HHS-certified laboratory means a laboratory that is certified to perform urine drug testing under the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs, which were published in the Federal Register on April 11, 1988 (53 FR 11970), and as amended, June 9, 1994 (59 FR 29908), November 13,1998 (63 FR 63483), and April 13, 2004 (69 FR 19643).

Illegal drug means, for the purposes of this regulation, any drug that is included in Schedules I–V of section 202 of the Controlled Substances Act [21 U.S.C. 812], but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

Increase in threat condition means an increase in the protective measure level as promulgated by an NRC Advisory.

Initial drug test means a test to differentiate "negative" specimens from those that require confirmatory drug testing.

Initial validity test means a first test used to determine whether a specimen is adulterated, diluted, or substituted, and may require confirmatory validity testing.

Invalid result means the result reported by an HHS-certified laboratory for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, contains inconsistent physiological constituents, or has an

endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

Legal action means a formal action taken by a law enforcement authority or court of law, including an arrest, an indictment, the filing of charges, a conviction, or the mandated implementation of a plan for substance abuse treatment in order to avoid a permanent record of an arrest or conviction, in response to any of the following activities:

(1) The use, sale, or possession of illegal drugs;

(2) The abuse of legal drugs or alcohol; or

(3) The refusal to take a drug or alcohol test.

Licensee testing facility means a drug testing facility that is operated by a licensee or other entity who is subject to this part to perform initial tests of urine specimens.

Limit of detection (LOD) means the lowest concentration of an analyte that an analytical procedure can reliably detect, which could be significantly lower than the established cutoff levels.

Limit of quantitation (LOQ) means the lowest concentration of an analyte at which the concentration of the analyte can be accurately determined under defined conditions.

Medical Review Officer (MRO) means a licensed physician who is responsible for receiving laboratory results generated by a Part 26 drug testing program and who has the appropriate medical training to properly interpret and evaluate an individual's non-negative test results together with his or her medical history and any other relevant biomedical information.

Nominal means the limited flexibility that is permitted in meeting a scheduled due date for completing a recurrent activity that is required under this part, such as the nominal 12-month frequency required for FFD refresher training in §26.29(c)(2) and the nominal 12-month

frequency required for certain audits in §26.41(c)(1). Completing a recurrent activity at a nominal frequency means that the activity may be completed within a period that is 25 percent longer or shorter than the period required in this part. The next scheduled due date would be no later than the current scheduled due date plus the required frequency for completing the activity.

Non-negative test result means a report by the licensee testing facility or the HHS-certified laboratory that a urine specimen meets the criteria for substitution established in this part or is positive for a drug, drug metabolite, or adulterant at a concentration equal to or greater than the designated cutoff levels, or the results of a test of oral fluids or breath that indicate the presence of alcohol at a concentration equal to or greater than the cutoff levels established by the FFD program or as specified in this part. A non-negative test result may be obtained from any initial or confirmatory drug, validity, or alcohol test.

Other entity means any corporation, firm, partnership, limited liability company, association, C/V, or other organization who is subject to this part under §26.3(c) and (d), but is not licensed by the NRC.

Oxidizing adulterant means a substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drugs or drug metabolites, or a substance that affects the reagents in either the initial or confirmatory drug test. Examples of these agents include, but are not limited to, nitrites, pyridinium chlorochromate, chromium (VI), bleach, iodine/iodide, halogens, peroxidase, and peroxide.

Potentially disqualifying FFD information means information demonstrating that an individual has —

(1) Violated a licensee's or other entity's FFD policy;

(2) Had authorization denied or terminated unfavorably under §§26.61(d), 26.63(d), 26.65(h), 26.67(c), 26.69(f), or 26.75(b) through (e);

(3) Used, sold, or possessed illegal drugs;

(4) Abused legal drugs or alcohol;

(5) Subverted or attempted to subvert a drug or alcohol testing program;

(6) Refused to take a drug or alcohol test;

(7) Been subjected to a plan for substance abuse treatment (except for self-referral); or

(8) Had legal action or employment action, as defined in this section, taken for alcohol or drug use.

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

Quality control sample means a sample used to evaluate whether an analytical procedure is operating within predefined tolerance limits. Calibrators, controls, negative samples, and blind samples are collectively referred to as “quality control samples” and each is individually referred to as a “sample.”

Reviewing official means the designated licensee or other entity’s employee who is responsible for reviewing and evaluating any potentially disqualifying FFD information about an individual, including, but not limited to, the results of a determination of fitness, as defined in §26.189, in order to determine whether the individual may be granted or maintain authorization.

Standard means a reference material of known purity or a solution containing a reference material at a known concentration.

Strategic special nuclear material (SSNM) means uranium-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope), uranium-233, or plutonium.

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

Substituted specimen means a specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human physiology.

Subversion and subvert the testing process mean a willful act to avoid being tested or to bring about an inaccurate drug or alcohol test result for oneself or others at any stage of the testing process (including selection and notification of individuals for testing, specimen collection, specimen analysis, test result reporting), and adulterating, substituting, or otherwise causing a specimen to provide an inaccurate test result.

Transporter means a general licensee, under 10 CFR 70.20(a), who is authorized to possess formula quantities of SSNM, in the regular course of carriage for another or storage incident thereto, and includes the driver or operator of any conveyance, and the accompanying guards or escorts.

Validity screening test means the use of a non-instrumented testing device to determine the need for initial validity testing of a urine specimen.

§26.7 Interpretations.

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

§26.8 Information collection requirements: OMB approval.

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

(b) The approved information collection requirements contained in this part appear in §§26.9, 26.27, 26.29, 26.31, 26.33, 26.35, 26.37, 26.39, 26.41, 26.55, 26.57, 26.59, 26.61, 26.63, 26.65, 26.69, 26.75, 26.77, 26.85, 26.87, 26.91, 26.93, 26.95, 26.97, 26.99, 26.101, 26.103, 26.107, 26.109, 26.111, 26.113, 26.115, 26.117, 26.119, 26.125, 26.127, 26.129, 26.135, 26.137, 26.139, 26.153, 26.155, 26.157, 26.159, 26.163, 26.165, 26.167, 26.169, 26.183, 26.185, 26.187, 26.189, 26.197, 26.199, 26.201, 26.211, 26.213, 26.215, 26.217, 26.219, and 26.221.

§26.9 Specific Exemptions.

Upon application of any interested person or upon its own initiative, the Commission may grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

§26.11 Communications.

Except where otherwise specified in this part, all communications, applications, and reports concerning the regulations in this part must be sent either by mail addressed: ATTN: NRC Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 8:15 a.m. and 4:00 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at http://www.nrc.gov/site-help/eie.html, by calling (301) 415-6030, by e-mail at EIE@nrc.gov, or by writing to the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. Copies of all communications must be sent to the appropriate regional office and resident inspector (addresses for the NRC Regional Offices are listed in Appendix D to Part 20 of this chapter).

Subpart B – Program Elements

§26.21 Fitness-for-duty program.

Licensees and other entities who are subject to this part must establish, implement, and maintain FFD programs in accordance with the applicable requirements of this part. Fitness-for-duty programs subject to this part may rely upon the FFD program or program elements of a

C/V, as defined in §26.5, if the C/V's FFD program or program elements meet the applicable requirements of this part.

§26.23 Performance objectives.

Fitness-for-duty programs must —

(a) Provide high assurance that individuals who are subject to this part are trustworthy and reliable as demonstrated by the avoidance of substance abuse;

(b) Provide reasonable assurance that individuals who are subject to this part are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

(c) Provide reasonable measures for the early detection of individuals who are not fit to perform the job duties that require them to be subject to this part;

(d) Provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol; and

(e) Provide reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety.

§26.25 Individuals subject to the fitness-for-duty program.

(a) Individuals whose job duties require them to have the following types of access, or to perform the following activities are subject to the FFD program:

(1) All persons who are granted unescorted access to nuclear power plant protected areas;

(2) All persons who are required by a licensee to physically report to the licensee's Technical Support Center or Emergency Operations Facility, in accordance with licensee emergency plans and procedures;

(3) SSNM licensee and transporter personnel who —

(i) Are granted unescorted access to Category IA Material;

(ii) Create or have access to procedures or records for safeguarding SSNM;

(iii) Measure Category IA Material;

(iv) Transport or escort Category IA Material; or

(v) Guard Category IA Material;

(4) All FFD program personnel who are involved in the day-to-day operations of the program, as defined by the licensee’s or other entity’s procedures, and who —

(i) Can link test results with the individual who was tested before an FFD policy violation determination is made, including, but not limited to the MRO;

(ii) Make determinations of fitness;

(iii) Make authorization decisions;

(iv) Are involved in selecting or notifying individuals for testing; or

(v) Are involved in the collection or on-site testing of specimens.

(b) The following individuals are not subject to the FFD program:

(1) Individuals who are not employed by the licensee’s or other entity’s FFD program, who do not routinely provide FFD program services, and whose normal workplace is not at the

licensee's or other entity's facility, but who may be called upon to provide an FFD program service, including, but not limited to, collecting specimens for drug and alcohol testing, performing behavioral observation, or providing input to a determination of fitness. Such individuals may include, but are not limited to, hospital, employee assistance program (EAP) or substance abuse treatment facility personnel, or other medical professionals;

(2) NRC employees, law enforcement personnel, or offsite emergency fire and medical response personnel while responding on site; and

(3) SSNM transporter personnel who are subject to U.S. Department of Transportation drug and alcohol FFD programs that require random testing for drugs and alcohol.

(c) Individuals who are subject to this part and who are also subject to a program regulated by another Federal agency or State need be covered by only those elements of a Part 26 FFD program that are not included in the Federal agency or State program, as long as all of the following conditions are met:

(1) The individuals are subject to pre-access (or pre-employment), random, for-cause, and post-event testing for the drugs and drug metabolites specified in §26.31(d)(1) at or below the cutoff levels specified in §26.163(a)(1) for initial drug testing and in §26.163(b)(1) for confirmatory drug testing;

(2) The individuals are subject to pre-access (or pre-employment), random, for-cause, and post-event testing for alcohol at or below the cutoff levels specified in §26.103(a) and breath specimens are subject to confirmatory testing, if required, with an evidential breath testing device that meets the requirements specified in §26.91;

(3) Urine specimens are tested for validity and the presence of drugs and drug metabolites at a laboratory certified by HHS;

(4) Training is provided to address the knowledge and abilities listed in §26.29(a)(1) through (10);

(5) An impartial and objective procedure is provided for the review and reversal of any findings of an FFD policy violation; and

(6) Provisions are made to ensure that the testing agency or organization notifies the licensee or other entity granting authorization of any FFD policy violation.

(d) Individuals who have applied for authorization to have the types of access or perform the activities described in paragraph (a) of this section shall be subject to the applicable requirements of this part and provided with the applicable protections of this part.

§26.27 Written policy and procedures.

(a) General. Each licensee and other entity who is subject to this part shall establish, implement, and maintain written policies and procedures to meet the general performance objectives and applicable requirements of this part.

(b) Policy. The FFD policy statement must be clear, concise, and readily available, in its most current form, to all individuals who are subject to the policy. Methods of making the statement readily available include, but are not limited to, posting the policy in multiple work areas, providing individuals with brochures, or allowing individuals to print the policy from a computer. The policy statement must be written in sufficient detail to provide affected

individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy. At a minimum, the written policy statement must —

(1) Describe the consequences of the following actions:

(i) The use, sale, or possession of illegal drugs on or off site;

(ii) The abuse of legal drugs and alcohol; and

(iii) The misuse of prescription and over-the-counter drugs;

(2) Describe the requirement that individuals who are notified that they have been selected for random testing must report to the collection site within the time period specified by the licensee or other entity;

(3) Describe the consequences of refusals to provide a specimen for testing, as well as the consequences of subverting or attempting to subvert the testing process;

(4) Prohibit the consumption of alcohol, at a minimum, —

(i) Within an abstinence period of 5 hours preceding the individual's arrival at the licensee's or other entity's facility, except as permitted in §26.27(c)(3); and

(ii) During the period of any tour of duty;

(5) Convey that abstinence from alcohol for the 5 hours preceding any scheduled tour of duty is considered to be a minimum that is necessary, but may not be sufficient, to ensure that the individual is fit for duty;

(6) Address other factors that could affect FFD, such as mental stress, fatigue, or illness, and the use of prescription and over-the-counter medications that could cause impairment;

(7) Provide a description of any program that is available to individuals who are seeking assistance in dealing with drug, alcohol, fatigue, or other problems that could adversely affect an individual's ability to safely and competently perform the job duties that require an individual to be subject to this part;

(8) Describe the consequences of violating the policy;

(9) Describe the individual's responsibility to report legal actions, as defined in §26.5;

(10) Describe the responsibilities of managers, supervisors, and escorts to report FFD concerns; and

(11) Describe the individual's responsibility to report FFD concerns.

(c) Procedures. Each licensee and other entity who is subject to this part shall prepare, implement, and maintain written procedures that describe the methods to be used in implementing the FFD policy and the requirements of this part. The procedures must —

(1) Describe the methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the privacy and due process rights of an individual who provides a specimen, procedures for protecting the integrity of the specimen, and procedures used to ensure that the test results are valid and attributable to the correct individual;

(2) Describe immediate and followup actions that will be taken, and the procedures to be used, in those cases in which individuals who are subject to this part are determined to have —

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

(ii) Consumed alcohol to excess before the mandatory pre-work abstinence period, during the mandatory pre-work abstinence period, or while on duty, as determined by a test that measures BAC;

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

(iv) Refused to provide a specimen for analysis; or

(v) Had legal action taken relating to drug or alcohol use, as defined in §26.5;

(3) Describe the process that the licensee or other entity will use to ensure that individuals who are called in to perform an unscheduled working tour are fit for duty. Consumption of alcohol during the 5-hour abstinence period required in paragraph (b)(4)(i) of this section may not by itself preclude a licensee or other entity from using individuals who are needed to respond to an emergency. At a minimum, —

(i) The procedure must require the individual who is called in to state whether the individual considers himself or herself fit for duty and whether he or she has consumed alcohol within the pre-duty abstinence period stated in the policy;

(ii) If the individual has consumed alcohol within this period and the individual is called in, the procedure must —

(A) Require a determination of fitness by breath alcohol analysis or other means;

(B) Require the establishment of controls and conditions under which the individual who has been called in can perform work, if necessary; and

(C) State that no sanctions may be imposed on an individual who is called in to perform an unscheduled working tour and has consumed alcohol within the pre-duty abstinence period stated in the policy.

(iii) If the individual reports that he or she considers himself or herself to be unfit for duty for other reasons, including illness, fatigue, or other potentially impairing conditions, and the

individual is called in, the procedure must require the establishment of controls and conditions under which the individual can perform work, if necessary;

(4) Describe the process to be followed if an individual's behavior raises a concern regarding the possible use, sale, or possession of illegal drugs on or off site; the possible possession or consumption of alcohol on site; or impairment from any cause which in any way could adversely affect the individual's ability to safety and competently perform his or her duties. The procedure must require that individuals who have an FFD concern about another individual's behavior shall contact the personnel designated in the procedures to report the concern.

(d) Review. The NRC may, at any time, review the written policy and procedures to assure that they meet the performance objectives and requirements of this part.

§26.29 Training.

(a) Training content. Licensees and other entities shall ensure that individuals who are subject to this part have the following knowledge and abilities (KAs):

(1) Knowledge of the policy and procedures that apply to the individual, the methods that will be used to implement them, and the consequences of violating the policy and procedures;

(2) Knowledge of the individual's role and responsibilities under the FFD program;

(3) Knowledge of the roles and responsibilities of others, such as the MRO and the human resources, FFD, and EAP staffs;

(4) Knowledge of the EAP services available to the individual;

(5) Knowledge of the personal and public health and safety hazards associated with abuse of illegal and legal drugs and alcohol;

(6) Knowledge of the potential adverse effects on job performance of prescription and over-the-counter drugs, alcohol, dietary factors, illness, mental stress, and fatigue;

(7) Knowledge of the prescription and over-the-counter drugs and dietary factors that have the potential to affect drug and alcohol test results;

(8) Ability to recognize illegal drugs and indications of the illegal use, sale, or possession of drugs;

(9) Ability to observe and detect performance degradation, indications of impairment, or behavioral changes; and

(10) Knowledge of the individual's responsibility to report an FFD concern and the ability to initiate appropriate actions, including referrals to the EAP and person(s) designated by the licensee or other entity to receive FFD concerns.

(b) Comprehensive examination. Individuals who are subject to this part shall demonstrate the successful completion of training by passing a comprehensive examination that addresses the KAs in paragraph (a) of this section. The examination must include a comprehensive random sampling of all KAs with questions that test each KA, including at least one question for each KA. The minimum passing score required must be 80 percent. Remedial training and testing are required for individuals who fail to answer correctly at least 80 percent of the test questions. The examination may be administered using a variety of media, including, but not limited to, hard-copy test booklets with separate answer sheets or computer-based questions.

(c) Training administration. Licensees and other entities shall ensure that individuals who are subject to this part are trained, as follows:

(1) Training must be completed before the licensee or other entity grants initial authorization, as defined in §26.55, and must be current before the licensee or other entity grants an authorization update, as defined in §26.57, or authorization reinstatement, as defined in §26.59;

(2) Individuals shall complete refresher training on a nominal 12-month frequency, or more frequently where the need is indicated. Individuals who pass a comprehensive annual examination that meets the requirements in paragraph (b) of this section may forgo the refresher training; and

(3) Initial and refresher training may be delivered using a variety of media (including, but not limited to, classroom lectures, required reading, video, or computer-based training systems). The licensee or other entity shall monitor the completion of training and provide a qualified instructor or designated subject matter expert to answer questions during the course of training.

(d) Acceptance of training. Licensees and other entities may accept training of individuals who have been subject to another Part 26 program and who have, within the past 12 months, either had initial or refresher training, or have successfully passed a comprehensive examination that meets the requirements in paragraph (b) of this section.

§26.31 Drug and alcohol testing.

(a) General. To provide a means to deter and detect substance abuse, licensees and other entities who are subject to this part shall implement drug and alcohol testing programs for individuals who are subject to this part.

(b) Assuring the honesty and integrity of FFD program personnel.

(1) Licensees and other entities who are subject to this part shall carefully select and monitor FFD program personnel, as defined in §26.25(a)(4), based upon the highest standards for honesty and integrity, and shall implement measures to ensure that these standards are maintained. The measures must ensure that the honesty and integrity of these individuals are not compromised and that FFD program personnel are not subject to influence attempts attributable to personal relationships with any individuals who are subject to testing, an undetected or untreated substance abuse problem, or other factors. At a minimum, these measures must include the following considerations:

(i) Licensees and other entities shall complete appropriate background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel before assignment to tasks directly associated with administration of the FFD program. The background investigations, credit and criminal history checks, and psychological assessments conducted in order to grant unescorted access authorization to individuals under a nuclear power plant licensee's access authorization program are acceptable to meet the requirements of this paragraph. The credit and criminal history checks and psychological assessments must be updated nominally every 5 years;

(ii) Individuals who have personal relationships with the individual being tested may not perform any assessment or evaluation procedures, including, but not limited to, determinations

of fitness. These personal relationships may include, but are not limited to, supervisors, coworkers within the same work group, and relatives of the donor.

(iii) Except if a directly observed collection is required, a collector who has a personal relationship with the donor may collect specimens from the donor only if the integrity of specimen collections in these instances is assured through the following means:

(A) The collection must be monitored by an individual who does not have a personal relationship with the donor and who is designated by the licensee or other entity for this purpose, including, but not limited to, security force or quality assurance personnel; and

(B) Individuals who are designated to monitor collections in these instances shall be trained to monitor specimen collections and the preparation of specimens for transfer or shipping in accordance with the requirements of this part;

(iv) If a specimen must be collected under direct observation, the collector or an individual who serves as the observer, as permitted under §26.115(e), may not have a personal relationship with the donor; and

(v) FFD program personnel shall be subject to a behavioral observation program designed to assure that they continue to meet the highest standards of honesty and integrity. When an MRO and MRO staff are on site at a licensee's or other entity's facility, the MRO and MRO staff shall be subject to behavioral observation.

(2) Licensees and other entities who are subject to this part may rely upon a local hospital or other organization that meets the requirements of 49 CFR Part 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs" (65 FR 41944; August 9, 2001) to collect specimens for drug and alcohol testing from the FFD program personnel listed in §26.25(a)(4).

(c) Conditions for testing. Licensees and other entities shall administer drug and alcohol tests to individuals who are subject to this part under the following conditions:

(1) Pre-access. In order to grant initial, updated, or reinstated authorization to an individual, as specified in Subpart C;

(2) For cause. In response to an individual's observed behavior or physical condition indicating possible substance abuse or after receiving credible information that an individual is engaging in substance abuse, as defined in §26.5;

(3) Post-event. As soon as practical after an event involving a human error that was committed by an individual who is subject to this part, where the human error may have caused or contributed to the event. The licensee or other entity shall test the individual(s) who committed the error(s), and need not test individuals who were affected by the event but whose actions likely did not cause or contribute to the event. The individual(s) who committed the human error(s) shall be tested if the event resulted in —

(i) A significant illness or personal injury to the individual to be tested or another individual, which within 4 hours after the event is recordable under the Department of Labor standards contained in 29 CFR 1907.4, and subsequent amendments thereto, and results in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, loss of consciousness, or other significant illness or injury as diagnosed by a physician or other licensed health care professional, even if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness;

(ii) A radiation exposure or release of radioactivity in excess of regulatory limits; or

(iii) Actual or potential substantial degradations of the level of safety of the plant;

(4) Followup. As part of a followup plan to verify an individual's continued abstinence from substance abuse; and

(5) Random. On a statistically random and unannounced basis, so that all individuals in the population subject to testing have an equal probability of being selected and tested.

(d) General requirements for drug and alcohol testing.

(1) Substances tested. At a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol.

(i) In addition, licensees and other entities may consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other drugs with abuse potential are being used in the geographical locale of the facility and by the local workforce that may not be detected in the panel of drugs and drug metabolites specified in paragraph (d)(1) of this section.

(A) When appropriate, the licensee or other entity may add other drugs identified in accordance with paragraph (i) above to the panel of substances for testing, but only if the additional drugs are listed in Schedules I–V of section 202 of the Controlled Substances Act [21 U.S.C. 812].

(B) The licensee or other entity shall establish appropriate cutoff limits for these substances.

(C) The licensee or other entity shall establish rigorous testing procedures for these substances that are consistent with the intent of this part, so that the MRO can evaluate the use of these substances.

(D) The licensee or other entity may not conduct an analysis for any drug or drug metabolites except those identified in paragraph (d)(1) of this section unless the assay and cutoff levels to be used are certified in writing as scientifically sound and legally defensible by an independent, qualified forensic toxicologist. The forensic toxicologist may not be an employee of the licensee or entity, and shall either be a Diplomate of the American Board of Forensic Toxicology or currently hold, or would be eligible to hold, the position of Responsible Person at an HHS-certified laboratory, as specified in §26.155(a) of this part. All new assays and cutoff levels must be properly validated in accordance with established forensic toxicological standards before implementation. Certification of the assay and cutoff levels is not required if the HHS Guidelines are revised to authorize use of the assay in testing for the additional drug or drug metabolites and the licensee or other entity uses the cutoff levels established in the HHS Guidelines for the drug or drug metabolites, or if the licensee or other entity received written approval of the NRC to test for the additional drug or drug metabolites before **[Insert implementation date of final rule]**.

(ii) When conducting post-event, followup, and for-cause testing, as defined in §26.31(c), licensees and other entities may test for any drugs listed on Schedules I–V of section 202 of the Controlled Substances Act [21 U.S.C. 812] that an individual is suspected of having abused, and may consider any drugs or metabolites so detected when determining appropriate action under Subpart D of this part. If the drug or metabolites for which testing will be performed under this paragraph are not included in the FFD program's drug panel, the assay and cutoff levels to be used in testing for the additional drugs must be certified by a forensic toxicologist in accordance with paragraph (d)(1)(i)(D) of this section. Test results that fall below the established cutoff levels may not be considered when determining appropriate action under Subpart D of this part.

(2) Random testing. Random testing must —

(i) Be administered in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected. At a minimum, the FFD program shall —

(A) Take reasonable steps to either conceal from the workforce that collections will be performed during a scheduled collection period or create the appearance that specimens are being collected during a portion of each day on at least 4 days in each calendar week at each site; and

(B) Collect specimens on an unpredictable schedule, including weekends, backshifts, and holidays, and at various times during a shift;

(ii) At a minimum, be administered by the FFD program on a nominal weekly frequency;

(iii) Require individuals who are selected for random testing to report to the collection site as soon as reasonably practicable after notification, within the time period specified in the FFD program policy;

(iv) Ensure that all individuals in the population subject to testing have an equal probability of being selected and tested. Individuals who are off site when selected for testing, and not reasonably available for testing when selected, shall be tested at the earliest reasonable and practical opportunity when both the donor and collectors are available to collect specimens for testing and without prior notification to the individual that he or she has been selected for testing;

(v) Provide that an individual completing a test is immediately eligible for another unannounced test; and

(vi) Ensure that the sampling process used to select individuals for random testing provides that the number of random tests performed annually is equal to at least 50 percent of the population that is subject to the FFD program.

(3) Drug testing.

(i) Testing of urine specimens for drugs, except initial tests performed by licensee testing facilities under paragraph (d)(3)(ii) of this section, must be performed in a laboratory that is certified by HHS for that purpose, consistent with its standards and procedures for certification. Specimens sent to HHS-certified laboratories must be subject to initial validity and drug testing by the laboratory. Specimens that yield non-negative initial validity or drug test results must be subject to confirmatory testing by the laboratory, except for invalid specimens that cannot be tested. Licensees and other entities shall ensure that laboratories report results for all specimens sent for testing, including blind performance test samples.

(ii) Licensees and other entities may conduct validity screening and initial validity and drug tests of urine aliquots to determine which specimens are valid and negative and need no further testing, provided that the licensee's or other entity'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.

(iii) At a minimum, licensees and other entities shall apply the cutoff levels specified in §26.163(a)(1) for initial drug testing and in §26.163(b)(1) for confirmatory drug testing. At their discretion, licensees and other entities may implement programs with lower cutoff levels for drug testing.

(A) If a licensee or other entity implements lower cutoff levels, and the MRO determines that an individual has violated the FFD policy using the licensee's or other entity's more stringent cutoff levels, the individual shall be subject to all management actions and sanctions

required by the licensee's or other entity's FFD policy and this part, as if the individual had a confirmed positive drug test result using the cutoff levels specified in this part. The licensee or other entity shall document the more stringent cutoff levels in any written policies and procedures in which cutoff levels for drug testing are described.

(B) The licensee or other entity shall uniformly apply the cutoff levels listed in §26.163(a)(1) for initial drug testing and in §26.163(b)(1) for confirmatory drug testing, or any more stringent cutoff levels implemented by the FFD program, to all tests performed under this part and equally to all individuals who are tested under this part, except as permitted in §§26.31(d)(1)(ii) and 26.163(a)(2).

(C) In addition, the scientific and technical suitability of any more stringent cutoff levels must be evaluated and certified, in writing, by a forensic toxicologist who meets the requirements set forth in §26.31(d)(1)(i)(D). Certification of the more stringent cutoff levels is not required if the HHS Guidelines are revised to lower the cutoff levels for the drug or drug metabolites in Federal workplace drug testing programs and the licensee or other entity implements the cutoff levels published in the HHS Guidelines, or if the licensee or other entity received written approval of the NRC to test for lower cutoff levels before **[Insert implementation date of final rule]**

(4) Alcohol testing. Initial tests for alcohol must be administered by breath or oral fluids analysis using alcohol analysis devices that meet the requirements of §26.91(a). If the initial test shows a BAC of 0.02 percent or greater, a confirmatory test for alcohol must be performed. The confirmatory test must be performed with an evidential breath testing device that meets the requirements of §26.91(b).

(5) Medical conditions.

(i) If an individual has a medical condition that makes collection of breath, oral fluids, or urine specimens difficult or hazardous, the MRO may authorize an alternative evaluation process, tailored to the individual case, to meet the requirements of this part for drug and alcohol testing. The alternative process must include measures to prevent subversion and achieve results that are comparable to those produced by urinalysis for drugs and breath analysis for alcohol.

(ii) If an individual requires medical attention, including, but not limited to, an injured worker in an emergency medical facility who is required to have a post-event test, treatment may not be delayed to conduct drug and alcohol testing.

(6) Limitations of testing. Specimens collected under NRC regulations may only be designated or approved for testing as described in this part and may not be used to conduct any other analysis or test without the written permission of the donor. Analyses and tests that may not be conducted include, but are not limited to, DNA testing, serological typing, or any other medical or genetic test used for diagnostic or specimen identification purposes.

§26.33 Behavioral observation.

Licensees and other entities who are subject to this part shall ensure that the individuals listed in §26.25(a) and (c), if necessary, are subject to behavioral observation. Behavioral observation must be performed by individuals who are trained in accordance with §26.29 to detect behaviors that may indicate possible use, sale, or possession of illegal drugs; use or possession of alcohol on site or while on duty; or impairment from fatigue or any cause that, if left unattended, may constitute a risk to the health and safety of the public. Individuals who are

subject to this part shall report any FFD concerns about other individuals who are subject to this part to the personnel designated in the FFD policy.

§26.35 Employee assistance programs.

(a) Each licensee and other entity who is subject to this part shall maintain an EAP to strengthen the FFD program by offering confidential assessment, short-term counseling, referral services, and treatment monitoring to its employees who have problems that could adversely affect the employees' abilities to safely and competently perform their duties. Employee assistance programs must be designed to achieve early intervention and provide for confidential assistance.

(b) Licensees and other entities need not provide EAP services to a C/V's employees and individuals who have applied for, but have not yet been granted, authorization.

(c) The EAP staff shall protect the identity and privacy of any individual (including those who have self-referred) seeking assistance from the EAP, except if the individual waives the right to privacy in writing or a determination is made that the individual's condition or actions pose or have posed an immediate hazard to himself or herself or others.

(1) Licensees and other entities may not require the EAP to routinely report the names of individuals who self-refer to the EAP or the nature of the assistance the individuals sought.

(2) If EAP personnel determine that an individual poses or has posed an immediate hazard to himself or herself or others, EAP personnel shall so inform FFD program management, and need not obtain a written waiver of the right to privacy from the individual. The individual conditions or actions that EAP personnel shall report to FFD program management include, but are not limited to, substantive reasons to believe that the individual —

(i) Is likely to commit self-harm or harm to others;

(ii) Has been impaired from using drugs or alcohol while in a work status and has a continuing substance abuse disorder that makes it likely he or she will be impaired while in a work status in the future; or

(iii) Has ever engaged in any acts that would be reportable under §26.219(b)(1) through (b)(3).

(3) If a licensee or other entity receives a report from EAP personnel under paragraph (c)(2) of this section, the licensee or other entity shall ensure that the requirements of §§26.69(d) and 26.77(b) are implemented, as applicable.

§26.37 Protection of information.

(a) Each licensee or other entity who is subject to this part who collects personal information about an individual for the purpose of complying with this part, shall establish and maintain a system of files and procedures to protect the personal information. Licensees and other entities shall maintain and use such records with the highest regard for individual privacy.

(b) Licensees and other entities shall obtain a signed consent that authorizes the disclosure of the personal information collected and maintained under this part before disclosing the personal information, except for disclosures to the following individuals:

(1) The subject individual or his or her representative, when the individual has designated the representative in writing for specified FFD matters;

(2) Assigned MROs and MRO staff;

(3) NRC representatives;

(4) Appropriate law enforcement officials under court order;

(5) A licensee's or other entity's representatives who have a need to have access to the information in performing assigned duties, including determinations of fitness, audits of FFD programs, and human resources functions;

(6) The presiding officer in a judicial or administrative proceeding that is initiated by the subject individual;

(7) Persons deciding matters under review in §26.39; and

(8) Other persons pursuant to court order.

(c) Personal information that is collected under this part must be disclosed to other licensees and entities, including C/Vs, or their authorized representatives, who are legitimately seeking the information for authorization decisions as required by this part and who have obtained a signed release from the subject individual.

(d) Upon receipt of a written request by the subject individual or his or her designated representative, the licensee, other entity, HHS-certified laboratory, or MRO possessing such records shall promptly provide copies of all records pertaining to the determination of a violation of the FFD policy, including test results, MRO reviews, and management actions pertaining to the subject individual. The licensee or other entity shall obtain records related to the results of any relevant laboratory certification, review, or revocation-of-certification proceedings from the HHS-certified laboratory and provide them to the subject individual upon request.

(e) A licensee's or other entity's contracts with HHS-certified laboratories and licensee testing facility procedures must require that test records be maintained in confidence, except as provided in paragraphs (b), (c), and (d) of this section.

(f) This section does not authorize the licensee or other entity to withhold evidence of criminal conduct from law enforcement officials.

§26.39 Review process for fitness-for-duty policy violations.

(a) Each licensee and other entity who is subject to this part shall establish procedures for the review of a determination that an individual who they employ or who has applied for authorization has violated the FFD policy. The procedure must provide for an objective and impartial review of the facts related to the determination that the individual has violated the FFD policy.

(b) The procedure must provide notice to the individual of the grounds for the determination that the individual has violated the FFD policy, and must provide an opportunity for the individual to respond and submit additional relevant information.

(c) The procedure must ensure that the review is conducted by more than one individual and that the individuals who conduct the review are not associated with the administration of the FFD program (see the description of FFD program personnel in §26.25(a)(4)). The individuals who conduct the review may be management personnel.

(d) If the review finds in favor of the individual, the licensee or other entity shall update the relevant records to reflect the outcome of the review and delete or correct all information the review found to be inaccurate.

(e) Licensees and other entities need not provide a review procedure to a C/V's employee or applicant when the C/V is administering its own FFD program and the FFD policy violation was determined under the C/V's program.

§26.41 Audits and corrective action.

(a) General. Each licensee and other entity who is subject to this part is responsible for the continuing effectiveness of the FFD program, including FFD program elements that are provided by C/Vs, the FFD programs of any C/Vs that are accepted by the licensee or other entity, and the programs of the HHS-certified laboratories upon whom the licensee or other entity and its C/Vs rely. Each licensee and other entity shall ensure that these programs are audited and that corrective actions are taken to resolve any problems identified.

(b) FFD program. Each licensee and other entity who is subject to this part shall ensure that the entire FFD program is audited as needed, but no less frequently than nominally every 24 months. Licensees and other entities are responsible for determining the appropriate frequency, scope, and depth of additional auditing activities within the nominal 24-month period based on the 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."

(c) C/Vs and HHS-certified laboratories.

(1) FFD services that are provided to a licensee or other entity by C/V personnel who are off site or are not under the direct daily supervision or observation of the licensee's or other entity's personnel and HHS-certified laboratories must be audited on a nominal 12-month frequency.

(2) Audits of HHS-certified laboratories that are conducted for licensees and other entities who are subject to this part need not duplicate areas inspected in the most recent HHS certification inspection. However, the licensee and other entity shall review the HHS certification inspection records and reports to identify any areas in which the licensee or other entity uses services that the HHS certification inspection did not address. The licensee or other

entity shall ensure that any such areas are audited on a nominal 12-month frequency. Licensees and other entities need not audit organizations and professionals who may provide an FFD program service to the licensee or other entity, but who are not routinely involved in providing services to a licensee's or other entity's FFD program, as specified in §26.25(b)(1).

(d) Contracts.

(1) Licensees' and other entities' contracts with C/Vs and HHS-certified laboratories must reserve the right to audit the C/V, the C/V's subcontractors providing FFD program services, and the HHS-certified laboratories at any time, including at unannounced times, as well as to review all information and documentation that is reasonably relevant to the audits.

(2) Licensees' and other entities' contracts with C/Vs and HHS-certified laboratories must also permit the licensee or other entity to obtain copies of and take away any documents, including reviews and inspections pertaining to a laboratory's certification by HHS, and any other data that may be needed to assure that the C/V, its subcontractors, or the HHS-certified laboratory are performing their functions properly and that staff and procedures meet applicable requirements. In a contract with a licensee or other entity who is subject to this part, an HHS-certified laboratory may reasonably limit the use and dissemination of any documents copied or taken away by the licensee's or other entity's auditors in order to ensure the protection of proprietary information and donors' privacy.

(3) In addition, before awarding a contract, the licensee or other entity shall ensure completion of pre-award inspections and/or audits of the procedural aspects of the HHS-certified laboratory's drug-testing operations, except as provided in paragraph (g)(5) of this section.

(e) Conduct of audits. Audits must focus on the effectiveness of the FFD program or program element(s), as appropriate, and must be conducted by individuals who are qualified in

the subject(s) being audited. The individuals performing the audit of the FFD program or program element(s) shall be independent from both the subject FFD program's management and from personnel who are directly responsible for implementing the FFD program.

(f) Audit results. The result of the audits, along with any recommendations, must be documented and reported to senior corporate and site management. Each audit report must identify conditions that are adverse to the proper performance of the FFD program, the cause of the condition(s), and, when appropriate, recommended corrective actions. The licensee or other entity shall review the audit findings and take corrective actions, including re-auditing of the deficient areas where indicated, to preclude, within reason, repetition of the condition. The resolution of the audit findings and corrective actions must be documented.

(g) Sharing of audits. Licensees and other entities may jointly conduct audits, or may accept audits of C/Vs and HHS-certified laboratories that were conducted by other licensees and entities who are subject to this part, if the audit addresses the services obtained from the C/V or HHS-certified laboratory by each of the sharing licensees and other entities.

(1) Licensees and other entities shall review audit records and reports to identify any areas that were not covered by the shared or accepted audit.

(2) Licensees and other entities shall ensure that FFD program elements and services upon which the licensee or entity relies are audited, if the program elements and services were not addressed in the shared audit.

(3) Sharing licensees and other entities need not re-audit the same C/V or HHS-certified laboratory for the same period of time.

(4) Each sharing licensee and other entity shall maintain a copy of the shared audit and HHS certification inspection records and reports, including findings, recommendations, and corrective actions.

(5) If an HHS-certified laboratory loses its certification, in whole or in part, a licensee or other entity is permitted to immediately use another HHS-certified laboratory that has been audited within the previous 12 months by another NRC licensee or entity who is subject to this part. Within 3 months after the change, the licensee or other entity shall ensure that an audit is completed of any areas that have not been audited by another licensee or entity who is subject to this part within the past 12 months.

Subpart C – Granting and Maintaining Authorization

§26.51 Purpose.

This subpart contains FFD requirements for granting and maintaining authorization to have the types of access and be assigned to perform the job duties that are specified in §26.25(a).

§26.53 General provisions.

(a) In order to grant authorization to individuals, a licensee or other entity who is subject to this part shall meet the requirements in this subpart for initial authorization, authorization update, authorization reinstatement, or authorization with potentially disqualifying FFD information, as applicable.

(b) For individuals who have previously held authorization under this part but whose authorization has since been favorably terminated, the licensee or other entity shall implement

the requirements for either initial authorization, authorization update, or authorization reinstatement, based upon the total number of days that the individual's authorization is interrupted, to include the day after the individual's last period of authorization was terminated and the intervening days until the day upon which the licensee or other entity grants authorization to the individual. If potentially disqualifying FFD information is disclosed or discovered about an individual, licensees and other entities shall implement the applicable requirements in §26.69 in order to grant or maintain an individual's authorization.

(c) The licensee or other entity shall ensure that an individual has met the applicable FFD training requirements in §§26.29 and 26.197(c) before granting authorization to the individual.

(d) Licensees and other entities who are seeking to grant authorization to an individual who is subject to another FFD program that complies with this part may rely on the transferring FFD program to satisfy the requirements of this part. The individual may maintain his or her authorization if he or she continues to be subject to either the receiving FFD program or the transferring FFD program, or a combination of elements from both programs that collectively satisfy the requirements of this part.

§26.55 Initial authorization.

(a) Before granting authorization to an individual who has never held authorization under this part or whose authorization has been interrupted for a period of 3 years or more and whose last period of authorization was terminated favorably, the licensee or other entity shall —

(1) Obtain and review a self-disclosure in accordance with the applicable requirements of §26.61;

(2) Complete a suitable inquiry in accordance with the applicable requirements of §26.63;

(3) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(4) Ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of §26.67.

(b) If potentially disqualifying FFD information is disclosed or discovered, the licensee or other entity may not grant authorization to the individual, except in accordance with §26.69.

§26.57 Authorization update.

(a) Before granting authorization to an individual whose authorization has been interrupted for more than 365 days but less than 3 years and whose last period of authorization was terminated favorably, the licensee or other entity shall —

(1) Obtain and review a self-disclosure in accordance with the applicable requirements of §26.61;

(2) Complete a suitable inquiry in accordance with the applicable requirements of §26.63;

(3) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(4) Ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of §26.67.

(b) If potentially disqualifying FFD information is disclosed or discovered, the licensee or other entity may not grant authorization to the individual, except in accordance with §26.69.

§26.59 Authorization reinstatement.

(a) In order to grant authorization to an individual whose authorization has been interrupted for a period of more than 30 days but no more than 365 days and whose last period of authorization was terminated favorably, the licensee or other entity shall —

(1) Obtain and review a self-disclosure in accordance with the applicable requirements of §26.61;

(2) Complete a suitable inquiry in accordance with the requirements of §26.63 within 5 business days of reinstating authorization. If the suitable inquiry is not completed within 5 business days due to circumstances that are outside of the licensee's or other entity's control and the licensee or other entity is not aware of any potentially disqualifying information regarding the individual within the past 5 years, the licensee or other entity may maintain the individual's authorization for an additional 5 business days. If the suitable inquiry is not completed within 10 business days of reinstating authorization, the licensee or other entity shall administratively withdraw the individual's authorization until the suitable inquiry is completed;

(3) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(4) Ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of §26.67.

(b) If a licensee or other entity administratively withdraws an individual's authorization under paragraph (a)(2) of this section, and until the suitable inquiry is completed, the licensee

or other entity may not record the administrative action to withdraw authorization as an unfavorable termination and may not disclose it in response to a suitable inquiry conducted under the provisions of §26.63, a background investigation conducted under the provisions of this chapter, or any other inquiry or investigation. The individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information.

(c) Before granting authorization to an individual whose authorization has been interrupted for a period of no more than 30 days and whose last period of authorization was terminated favorably, the licensee or other entity shall —

(1) Obtain and review a self-disclosure in accordance with the applicable requirements of §26.61;

(2) If the individual's authorization was interrupted for more than 5 days, ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(3) Ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of §26.67.

(d) If potentially disqualifying FFD information is disclosed or discovered, the licensee or other entity may not grant authorization to the individual, except in accordance with §26.69.

§26.61 Self-disclosure and employment history.

(a) Before granting authorization, the licensee or other entity shall obtain a written self-disclosure and employment history from the individual who is applying for authorization, except as follows:

(1) If an individual previously held authorization under this part, and the licensee or other entity has verified that the individual's last period of authorization was terminated favorably, and the individual has been subject to a behavioral observation and arrest-reporting program that meets the requirements of this part throughout the period since the individual's last authorization was terminated, the granting licensee or other entity need not obtain the self-disclosure or employment history in order to grant authorization; and

(2) If the individual's last period of authorization was terminated favorably within the past 30 days, the licensee or other entity need not obtain the employment history.

(b) The written self-disclosure must —

(1) State whether the individual has —

(i) Violated a licensee's or other entity's FFD policy;

(ii) Had authorization denied or terminated unfavorably under §§26.61(d), 26.63(d), 26.65(h), 26.67(c), 26.69(f), or 26.75(b) through (e);

(iii) Used, sold, or possessed illegal drugs;

(iv) Abused legal drugs or alcohol;

(v) Subverted or attempted to subvert a drug or alcohol testing program;

(vi) Refused to take a drug or alcohol test;

(vii) Been subject to a plan for substance abuse treatment (except for self-referral); or

(viii) Had legal action or employment action, as defined in §26.5, taken for alcohol or drug use;

(2) Address the specific type, duration, and resolution of any matter disclosed, including, but not limited to, the reason(s) for any unfavorable termination or denial of authorization; and

(3) Address the shortest of the following periods:

(i) The past 5 years;

(ii) Since the individual's eighteenth birthday; or

(iii) Since the individual's last period of authorization was terminated, if authorization was terminated favorably within the past 3 years.

(c) The individual shall provide a list of all employers, including the current employer, if any, with dates of employment, for the shortest of the following periods:

(1) The past 3 years;

(2) Since the individual's eighteenth birthday; or

(3) Since authorization was last terminated, if authorization was terminated favorably within the past 3 years.

(d) Falsification of the self-disclosure statement or employment history is sufficient cause for denial of authorization.

§26.63 Suitable inquiry.

(a) The licensee or other entity shall conduct a suitable inquiry, on a best effort basis, to verify the individual's self-disclosed information and determine whether any potentially disqualifying FFD information is available, except if all of the following conditions are met:

(1) The individual previously held authorization under this part;

(2) The licensee or other entity has verified that the individual's last period of authorization was terminated favorably; and

(3) The individual has been subject to a behavioral observation and arrest-reporting program that meets the requirements of this part throughout the period of interruption.

(b) To meet the suitable inquiry requirement, licensees and other entities may rely upon the information that other licensees and entities who are subject to this part have gathered for previous periods of authorization. Licensees and other entities may also rely upon those licensees' and entities' determinations of fitness, as well as their reviews and resolutions of potentially disqualifying FFD information, for previous periods of authorization.

(c) The licensee or other entity shall conduct the suitable inquiry, on a best effort basis, by questioning both present and former employers.

(1) For the claimed employment period, the suitable inquiry must ascertain the reason for termination, eligibility for rehire, and other information that could reflect on the individual's fitness to be granted authorization.

(2) If the claimed employment was military service, the licensee or other entity who is conducting the suitable inquiry shall request a characterization of service, reason for separation, and any disciplinary actions related to potentially disqualifying FFD information. If the individual's last duty station cannot provide this information, the licensee or other entity may accept a hand-carried copy of the DD 214 presented by the individual which on face value appears to be legitimate. The licensee or other entity may also accept a copy of a DD 214 provided by the custodian of military records.

(3) If a company, previous employer, or educational institution to whom the licensee or other entity has directed a request for information refuses to provide information or indicates an inability or unwillingness to provide information within 3 business days of the request, the licensee or other entity shall document this refusal, inability, or unwillingness in the licensee's or other entity's record of the investigation, and obtain a confirmation of employment or

educational enrollment and attendance from at least one alternate source, with suitable inquiry questions answered to the best of the alternate source's ability. This alternate source may not have been previously used by the licensee or other entity to obtain information about the individual's character. If the licensee or other entity uses an alternate source because employer information is not forthcoming within 3 business days of the request, the licensee or other entity need not delay granting authorization to wait for any employer response.

(d) In response to another licensee's or other entity's inquiry and presentation of an individual's signed release authorizing the disclosure of information, a licensee or other entity shall disclose whether the subject individual's authorization was denied or terminated unfavorably as a result of a violation of an FFD policy and shall make available the information upon which the denial or unfavorable termination of authorization was based, including, but not limited to, drug or alcohol test results. The failure of an individual to authorize the release of information for the suitable inquiry is sufficient cause to deny authorization.

(e) In conducting a suitable inquiry, the licensee or other entity may obtain information and documents by electronic means, including, but not limited to, telephone, facsimile, or email. The licensee or other entity shall make a record of the contents of the telephone call and shall retain that record, and any documents or electronic files obtained electronically, in accordance with §§26.211 and 26.213(a), (b), and (c), as applicable.

(f) The licensee or other entity shall conduct the suitable inquiry as follows:

(1) Initial authorization. The period of the suitable inquiry must be the past 3 years or since the individual's eighteenth birthday, whichever is shorter. For the 1-year period immediately preceding the date upon which the individual applies for authorization, the licensee or other entity shall conduct the suitable inquiry with every employer, regardless of the length of employment. For the remaining 2-year period, the licensee or other entity shall conduct the

suitable inquiry with the employer by whom the individual claims to have been employed the longest within each calendar month, if the individual claims employment during the given calendar month.

(2) Authorization update. The period of the suitable inquiry must be the period since authorization was terminated. For the 1-year period immediately preceding the date upon which the individual applies for authorization, the licensee or other entity shall conduct the suitable inquiry with every employer, regardless of the length of employment. For the remaining period since authorization was terminated, the licensee or other entity shall conduct the suitable inquiry with the employer by whom the individual claims to have been employed the longest within each calendar month, if the individual claims employment during the given calendar month.

(3) Authorization reinstatement after an interruption of more than 30 days. The period of the suitable inquiry must be the period since authorization was terminated. The licensee or other entity shall conduct the suitable inquiry with the employer by whom the individual claims to have been employed the longest within the calendar month, if the individual claims employment during the given calendar month.

§26.65 Pre-access drug and alcohol testing.

(a) Purpose. This section contains pre-access testing requirements for granting authorization to an individual who either has never held authorization or whose last period of authorization was terminated favorably and about whom no potentially disqualifying FFD information has been discovered or disclosed that was not previously reviewed and resolved by a licensee or other entity who is subject to this part.

(b) Accepting tests conducted within the past 30 days. If an individual has negative results from drug and alcohol tests that were conducted in accordance with the requirements of this part before the individual applied for authorization from the licensee or other entity, and the specimens for such testing were collected within the 30-day period preceding the day upon which the licensee or other entity grants authorization to the individual, the licensee or other entity may rely upon the results of those drug and alcohol tests to meet the requirements for pre-access testing in this section.

(c) Initial authorization and authorization update. Before granting authorization to an individual who has never been authorized or whose authorization has been interrupted for a period of more than 365 days, the licensee or other entity shall verify that the results of pre-access drug and alcohol tests are negative. The licensee or other entity need not conduct pre-access testing if —

(1) An individual previously held authorization under this part and has been subject to both a drug and alcohol testing program that includes random testing and a behavioral observation and arrest reporting program which meet the requirements of this part from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization; or

(2) The licensee or other entity relies upon negative results from drug and alcohol tests that were conducted before the individual applied for authorization, as permitted under paragraph (b) of this section, and the individual remains subject to a behavioral observation and arrest reporting program that meets the requirements of this part, beginning on the date upon which the drug and alcohol testing was conducted through the date upon which the individual is granted authorization and thereafter.

(d) Authorization reinstatement after an interruption of more than 30 days.

(1) In order to reinstate authorization for an individual whose authorization has been interrupted for a period of more than 30 days but no more than 365 days, except as permitted in paragraph (d)(2) of this section, the licensee or other entity shall —

(i) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing before reinstating authorization; and

(ii) Verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until the drug test results are received.

(2) The licensee or other entity need not conduct pre-access testing of these individuals if —

(i) The individual previously held authorization under this part and has been subject both to a drug and alcohol testing program that includes random testing and a behavioral and arrest-reporting program that meet the requirements of this part from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization; or

(ii) The licensee or other entity relies upon negative results from drug and alcohol tests that were conducted before the individual applied for authorization, as permitted under paragraph (b) of this section, and the individual remains subject to a behavioral observation and arrest reporting program that meets the requirements of this part, beginning on the date upon which the drug and alcohol testing was conducted through the date upon which the individual is granted authorization.

(e) Authorization reinstatement after an interruption of 30 or fewer days.

(1) The licensee or other entity need not conduct pre-access testing before granting authorization to an individual whose authorization has been interrupted for 5 or fewer days.

(2) In order to reinstate authorization for an individual whose authorization has been interrupted for a period of more than 5 days but not more than 30 days, except as permitted in paragraph (e)(3) of this section, the licensee or other entity shall take the following actions:

(i) The licensee or other entity shall subject the individual to random selection for pre-access drug and alcohol testing at a one-time probability that is equal to or greater than the normal testing rate specified in §26.31(d)(2)(vi) calculated for a 30-day period;

(ii) If the individual is not selected for pre-access testing under this paragraph, the licensee or other entity need not perform pre-access drug and alcohol tests; or

(iii) If the individual is selected for pre-access testing under this paragraph, the licensee or other entity shall —

(A) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing before reinstating authorization; and

(B) Verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until negative drug test results are received.

(3) If the individual previously held authorization under this part and has been subject to both a drug and alcohol testing program that included random testing and a behavioral observation and arrest reporting program that meet the requirements of this part from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization, then the granting licensee or other entity need not conduct pre-access testing of the individual.

(f) Time period for testing. If pre-access testing is required under this section, the licensee or other entity must collect the specimens within the 30-day period that precedes the date upon which the licensee or entity grants authorization to an individual.

(g) Administrative withdrawal of authorization. If a licensee or other entity administratively withdraws an individual's authorization under paragraphs (d)(1)(ii) or (e)(2)(iii)(B) of this section, and until the drug test results are known, the licensee or other entity may not record the administrative action to withdraw authorization as an unfavorable termination. The individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information. Immediately upon receipt of negative test results, the licensee or other entity shall ensure that any matter that could link the individual to the temporary administrative action is eliminated from the tested individual's personnel record and other records.

(h) Sanctions for a confirmed non-negative pre-access test result. If an individual has confirmed non-negative test results from any drug, validity, or alcohol tests that may be required in this section, the licensee or other entity shall, at a minimum and as appropriate —

(1) Deny authorization to the individual, as required by §§26.75(b), (d), (e)(2), or (g);

(2) Terminate the individual's authorization, if it has been reinstated, in accordance with §§26.75(e)(1) or (f); or

(3) Grant authorization to the individual only in accordance with the requirements of §26.69.

§26.67 Random drug and alcohol testing of individuals who have applied for authorization.

(a) When the licensee or other entity collects specimens from an individual for any pre-access testing that may be required under §§26.65 or 26.69, and thereafter, the licensee or other entity shall subject the individual to random testing in accordance with §26.31(d)(2), except if —

(1) The licensee or other entity does not grant authorization to the individual; or

(2) The licensee or other entity relies upon drug and alcohol tests to meet the applicable requirements for pre-access testing that were conducted before the individual applied for authorization. If the licensee or other entity relies upon drug and alcohol tests that were conducted before the individual applied for authorization, the licensee or other entity shall subject the individual to random testing when the individual arrives at a licensee's or other entity's facility for in-processing and thereafter.

(b) If an individual is selected for one or more random tests after any applicable requirement for pre-access testing in §§26.65 or 26.69 has been met, the licensee or other entity may grant authorization before random testing is completed in accordance with §26.31(d)(2), if the individual has met all other applicable requirements for authorization.

(c) If an individual has confirmed non-negative test results from any drug, validity, or alcohol test required in this section, the licensee or other entity shall, at a minimum and as appropriate —

(1) Deny authorization to the individual, as required by §§26.75(b), (d), (e)(2), or (g);

(2) Terminate the individual's authorization, if it has been granted, as required by §§26.75(e)(1) or (f); or

(3) Grant authorization to the individual only in accordance with the requirements of §26.69.

§26.69 Authorization with potentially disqualifying fitness-for-duty information.

(a) Purpose. This section defines the management actions that licensees and other entities who are subject to this part shall take in order to grant or maintain, at the licensee's or other entity's discretion, the authorization of an individual who is in the following circumstances:

(1) Potentially disqualifying FFD information within the past 5 years has been disclosed or discovered about the individual by any means, including, but not limited to, the individual's self-disclosure, the suitable inquiry, drug and alcohol testing, the administration of the FFD program, a self-report of a legal action, behavioral observation, or other sources of information, including, but not limited to, any background investigation or credit and criminal history check conducted under the requirements of this chapter; and

(2) The potentially disqualifying FFD information has not been reviewed and favorably resolved by a previous licensee or other entity who is subject to this part.

(b) Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization. The requirements in this paragraph apply to individuals whose authorization was denied or terminated unfavorably for a first violation of an FFD policy involving a confirmed positive drug or alcohol test result and individuals whose authorization was denied for 5 years under §26.75(c), (d), (e)(2), or (f). In order to grant, and subsequently maintain, the individual's authorization, the licensee or other entity shall —

(1) Obtain and review a self-disclosure from the individual that addresses the shorter period of either the past 5 years or since the individual last held authorization, and verify that

the self-disclosure does not contain any previously undisclosed potentially disqualifying FFD information before granting authorization;

(2) Complete a suitable inquiry with every employer by whom the individual claims to have been employed during the period addressed in the self-disclosure in accordance with the requirements of §26.63, and obtain and review any records that other licensees or entities who are subject to this part may have developed related to the unfavorable termination or denial of authorization;

(3) If the individual was subject to a 5-year denial of authorization under this part, verify that he or she has abstained from substance abuse for at least the past 5 years;

(4) Ensure that an SAE conducts a determination of fitness and indicates that the individual is fit to safely and competently perform his or her duties.

(i) If the individual's authorization was denied or terminated unfavorably for a first confirmed positive drug or alcohol test result, ensure that clinically appropriate treatment plans are developed by the SAE before granting authorization;

(ii) If the individual was subject to a 5-year denial of authorization, ensure that any recommendations for treatment and followup testing from the SAE's determination of fitness are initiated before granting authorization; and

(iii) Verify that the individual is in compliance with, and successfully completes, any followup testing and treatment plans.

(5) Within 10 business days before granting authorization, perform a pre-access alcohol test, collect a specimen for drug testing under direct observation, and ensure that the individual is subject to random testing thereafter. Verify that the pre-access drug and alcohol test results are negative before granting authorization.

(6) If the individual's authorization was denied or terminated unfavorably for a first confirmed positive drug or alcohol test result and a licensee or other entity grants authorization to the individual, ensure that the individual is subject to unannounced testing at least quarterly for a period of 3 calendars years after the date upon which the individual is again granted authorization. Both random and followup tests, as defined in §26.31(c), satisfy this requirement. Verify that the individual has negative test results from a minimum of 15 tests distributed over the 3-year period, except as follows:

(i) If the individual does not continuously hold authorization during the 3-year period, the licensee or other entity shall ensure that at least one unannounced test is conducted in any quarter during which the individual holds authorization;

(ii) If the 15 tests are not completed within the 3-year period specified in this paragraph due to periods during which the individual does not hold authorization, the testing program may be extended up to 5 years to complete the 15 tests;

(iii) If the individual does not hold authorization during the 5-year period a sufficient number of times or for sufficient periods of time to complete the 15 tests required in this paragraph, the licensee or other entity shall ensure that an SAE conducts a determination of fitness to assess whether further followup testing is required and implement the SAE's recommendations; and

(7) Verify that any drug and alcohol tests required in this paragraph, and any other drug and alcohol tests that are conducted under this part since authorization was terminated or denied, yield results indicating no further drug abuse, as determined by the MRO after review, or alcohol abuse, as determined by the result of confirmatory alcohol testing.

(c) Granting authorization with other potentially disqualifying FFD information. The requirements in this paragraph apply to an individual who has applied for authorization, and

about whom potentially disqualifying FFD information has been discovered or disclosed that is not a first confirmed positive drug or alcohol test result or a 5-year denial of authorization. Before granting authorization to the individual, the licensee or other entity shall —

(1) Verify that the individual's self-disclosure and employment history addresses the applicable period in §26.61(b)(3);

(2) Complete a suitable inquiry with every employer by whom the individual claims to have been employed during the period addressed in the self-disclosure in accordance with the requirements of §26.63, and obtain and review any records that other licensees or entities who are subject to this part may have developed with regard to potentially disqualifying FFD information about the individual from the past 5 years;

(3) If the designated reviewing official determines that a determination of fitness is required, verify that a professional with the appropriate qualifications, as specified in §26.187(a), has indicated that the individual is fit to safely and competently perform his or her duties;

(4) Ensure that the individual is in compliance with, or has completed, any plans for treatment and drug and alcohol testing from the determination of fitness, which may include the collection of urine specimens under direct observation; and

(5) Verify that the results of pre-access drug and alcohol tests are negative before granting authorization, and that the individual is subject to random testing after the specimens have been collected for pre-access testing and thereafter.

(d) Maintaining authorization with other potentially disqualifying FFD information. If an individual is authorized when other potentially disqualifying FFD information is disclosed or discovered, in order to maintain the individual's authorization, the licensee or other entity shall —

(1) Ensure that the licensee's or other entity's designated reviewing official completes a review of the circumstances associated with the information;

(2) If the designated reviewing official concludes that a determination of fitness is required, verify that a professional with the appropriate qualifications, as specified in §26.187(a), has indicated that the individual is fit to safely and competently perform his or her duties; and

(3) If the reviewing official determines that maintaining the individual's authorization is warranted, implement any recommendations for treatment and followup drug and alcohol testing from the determination of fitness, which may include the collection of urine specimens under direct observation, and ensure that the individual successfully completes the treatment plans.

(e) Accepting followup testing and treatment plans from another Part 26 program. Licensees and other entities may rely upon followup testing, treatment plans, and determinations of fitness that were conducted in accordance with this part by another licensee or entity.

(1) If an individual leaves the FFD program in which a treatment and followup testing plan was required under paragraphs (b), (c), or (d) of this section, and is granted authorization by the same or another licensee or entity, the licensee or other entity who grants authorization to the individual shall ensure that any treatment and followup testing requirements are met, with accountability assumed by the granting licensee or other entity.

(2) If the previous licensee or other entity determined that the individual successfully completed any required treatment and followup testing, and the individual's last period of authorization was terminated favorably, the receiving licensee or entity may rely upon the previous determination of fitness and no further review or followup is required.

(f) Sanctions for confirmed non-negative drug and alcohol test results. If an individual has confirmed non-negative test results from any drug, validity, or alcohol test required in this section, the licensee or other entity shall, at a minimum and as appropriate —

(1) Deny authorization to the individual, as required by §§26.75(b), (d), (e)(2), or (g); or

(2) Terminate the individual's authorization, if it has been granted, as required by §§26.75(e)(1) or (f).

§26.71 Maintaining authorization.

(a) Individuals may maintain authorization under the following conditions:

(1) The individual complies with the licensee's or other entity's FFD policies to which he or she is subject, including the responsibility to report any legal actions, as defined in §26.5;

(2) The individual remains subject to a drug and alcohol testing program that complies with the requirements of this part, including random testing;

(3) The individual remains subject to a behavioral observation program that complies with the requirements of this part; and

(4) The individual successfully completes required FFD training, in accordance with the schedule specified in §26.29(c).

(b) If an authorized individual is not subject to an FFD program that meets the requirements of this part for more than 30 continuous days, then the licensee or other entity shall terminate the individual's authorization and the individual shall meet the requirements in this subpart, as applicable, to regain authorization.

Subpart D – Management Actions and Sanctions to be Imposed

§26.75 Sanctions.

(a) This section defines the minimum sanctions that licensees and other entities shall impose when an individual has violated the drug and alcohol provisions of an FFD policy. A licensee or other entity who is subject to this part may impose more stringent sanctions, except as specified in paragraph (h) of this section.

(b) Any act or attempted act to subvert the testing process, including, but not limited to, refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen, for any test required under this part must result in the immediate unfavorable termination of the individual's authorization and permanent denial of authorization thereafter.

(c) Any individual who is determined to have been involved in the sale, use, or possession of illegal drugs or the consumption of alcohol within a protected area of any nuclear power plant, within a facility that is licensed to possess or use formula quantities of SSNM, within a transporter's facility or vehicle, or while performing the job duties that require the individual to be subject to this part shall immediately have his or her authorization unfavorably terminated and denied thereafter for a minimum of 5 years from the date of the unfavorable termination of authorization.

(d) Any individual who resigns or withdraws his or her application for authorization before authorization is terminated or denied for a first violation of the FFD policy involving a confirmed positive drug or alcohol test result shall immediately have his or her authorization denied for a minimum of 5 years from the date of termination or denial. If an individual resigns or withdraws his or her application for authorization before his or her authorization is terminated or denied for any violation of the FFD policy, the licensee or other entity shall record the resignation or withdrawal, the nature of the violation, and the minimum sanction that would have been required under this part had the individual not resigned or withdrawn his or her application for authorization.

(e) Lacking any other evidence to indicate the use, sale, or possession of illegal drugs or consumption of alcohol on site, a confirmed positive drug or alcohol test result must be presumed to be an indication of off-site drug or alcohol use in violation of the FFD policy.

(1) The first violation of the FFD policy involving a confirmed positive drug or alcohol test result must, at a minimum, result in the immediate unfavorable termination of the individual's authorization for at least 14 days.

(2) Any subsequent confirmed positive drug or alcohol test result, including during an assessment or treatment period, must result in the denial of authorization for a minimum of 5 years from the date of denial.

(f) Paragraph (e) of this section does not apply to the misuse of prescription and over-the-counter drugs, except if the MRO determines that misuse of the prescription or over-the-counter drug represents substance abuse. Sanctions for misuse of prescription and over-the-counter drugs must be sufficient to deter misuse of those substances.

(g) For individuals whose authorization was denied for 5 years under paragraphs (c), (d), (e), or (f) of this section, any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization.

(h) A licensee or other entity who is subject to this part may not terminate an individual's authorization and may not subject the individual to other administrative action based solely on a non-negative test result from any validity screening, initial validity, or initial drug test, other than positive initial test results for marijuana or cocaine metabolites from a specimen that appears to be valid on the basis of either validity screening or initial validity testing performed at a licensee testing facility, unless other evidence, including information obtained under the process set forth in §26.189, indicates that the individual is impaired or might otherwise pose a safety hazard.

(i) With respect to initial drug test results from a licensee testing facility for marijuana and cocaine metabolites from a specimen that appears to be valid, licensee testing facility personnel may inform licensee or other entity management of the non-negative initial drug test result and the specific drugs or metabolites identified, and licensees or other entities may administratively withdraw the donor's authorization or take lesser administrative actions against the donor based on a positive initial drug test result from a specimen that appears to be valid, provided that the licensee or other entity complies with the following conditions:

(1) For the drug for which action will be taken, at least 85 percent of the specimens that were determined to be positive as a result of initial drug tests at the licensee testing facility during the past 12-month data reporting period submitted to the NRC under §26.217 were subsequently reported as positive by the HHS-certified laboratory as the result of confirmatory testing;

(2) There is no loss of compensation or benefits to the donor during the period of temporary administrative action;

(3) Immediately upon receipt of a negative report from the HHS-certified laboratory or MRO, any matter that could link the donor to the temporary administrative action is eliminated from the donor's personnel record and other records; and

(4) Licensees and other entities may not disclose the temporary administrative action against an individual whose initial drug test result is not subsequently confirmed by the MRO as a violation of the FFD policy in response to a suitable inquiry conducted under the provisions of §26.63, a background investigation conducted under the provisions of this chapter, or to any other inquiry or investigation.

(i) To ensure that no records are retained, access to the system of files and records must be provided to personnel who are conducting reviews, inquiries into allegations, or audits under the provisions of §26.41, and to NRC inspectors.

(ii) The licensee or other entity shall provide the donor with a written statement that the records specified in §26.213 and §26.215 have not been retained with respect to the temporary administrative action and shall inform the donor in writing that the temporary administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for self-disclosure of potentially disqualifying FFD information.

§26.77 Management actions regarding possible impairment.

(a) This section defines management actions that licensees and other entities must take when an individual who is subject to this part shows indications that he or she may not be fit to safely and competently perform his or her duties.

(b) If an individual appears to be impaired or the individual's fitness is questionable, except as permitted under §26.27(c)(3) and §26.199(e) and (f), the licensee or other entity shall

take immediate action to prevent the individual from performing the job duties that require him or her to be subject to this part.

(1) If an observed behavior or physical condition creates a reasonable suspicion of possible substance abuse, the licensee or other entity shall perform drug and alcohol tests and the results must be negative before the individual returns to performing the job duties that require the individual to be subject to this part. However, if the physical condition is the smell of alcohol with no other behavioral or physical indications of impairment, then only an alcohol test is required, and the results must be negative before the individual returns to performing his or her duties.

(2) If a licensee or C/V who is subject to Subpart I is certain that the observed behavior or physical condition is the result solely of fatigue, the licensee or C/V shall ensure that a fatigue assessment is conducted in accordance with §26.201 and need not perform drug and alcohol tests nor a determination of fitness under §26.189.

(3) For other indications of possible impairment that do not create a reasonable suspicion of substance abuse (or fatigue, in the case of licensees and C/Vs who are subject to Subpart I), the licensee or other entity may permit the individual to return to performing his or her job duties only after the impairing or questionable conditions are resolved and a determination of fitness indicates that the individual is fit to safely and competently perform his or her duties.

(c) If a licensee or other entity has a reasonable belief that an NRC employee or NRC contractor may be under the influence of any substance, or is otherwise unfit for duty, the licensee or other entity may not deny access but shall escort the individual. In any such instance, the licensee or other entity shall immediately notify the appropriate Regional Administrator by telephone, followed by written notification (e.g., email or fax) to document the

verbal notification. If the Regional Administrator cannot be reached, the licensee or other entity shall notify the NRC Operations Center.

Subpart E – Collecting Specimens for Testing

§26.81 Purpose.

This subpart contains requirements for collecting specimens for drug and alcohol testing.

§26.83 Specimens to be collected.

Except as permitted under §26.31(d)(5), licensees and other entities who are subject to this part shall —

(a) Collect either breath or oral fluids for initial tests for alcohol. Breath must be collected for confirmatory tests for alcohol; and

(b) Collect only urine specimens for both initial and confirmatory tests for drugs.

§26.85 Collector qualifications and responsibilities.

(a) Urine collector qualifications. Urine collectors shall be knowledgeable of the requirements of this part, the FFD policy and procedures of the licensee or other entity for whom collections are performed, and shall keep current on any changes to urine collection procedures. Collectors shall receive qualification training that meets the requirements of this paragraph and demonstrate proficiency in applying the requirements of this paragraph before

serving as a collector. At a minimum, qualification training must provide instruction on the following subjects:

(1) All steps necessary to complete a collection correctly and the proper completion and transmission of the custody-and-control form;

(2) Methods to address “problem” collections, including, but not limited to, collections involving “shy bladder” and attempts to tamper with a specimen;

(3) How to correct problems in collections; and

(4) The collector’s responsibility for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the donor, and avoiding any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(b) Alcohol collector qualifications. Alcohol collectors shall be knowledgeable of the requirements of this part, the FFD policy and procedures of the licensee or other entity for whom collections are performed, and shall keep current on any changes to alcohol collection procedures. Collectors shall receive qualification training meeting the requirements of this paragraph and demonstrate proficiency in applying the requirements of this paragraph before serving as a collector. At a minimum, qualification training must provide instruction on the following subjects:

(1) The alcohol testing requirements of this part;

(2) Operation of the particular alcohol testing device(s) [i.e., the alcohol screening devices (ASDs) or evidential breath testing devices (EBTs)] to be used, consistent with the most recent version of the manufacturers’ instructions;

(3) Methods to address “problem” collections, including, but not limited to, collections involving “shy lung” and attempts to tamper with a specimen;

(4) How to correct problems in collections; and

(5) The collector’s responsibility for maintaining the integrity of the specimen collection process, carefully ensuring the privacy of the donor, and avoiding any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(c) Alternative collectors. A medical professional, technologist, or technician may serve as a collector without meeting the collector qualification requirements in paragraphs (a) or (b) of this section, as applicable, if the individual’s normal workplace is not at the licensee’s or other entity’s facility and he or she —

(1) Is not employed by the licensee’s or other entity’s FFD program;

(2) Does not routinely provide FFD program services to the licensee or other entity;

(3) Is licensed or otherwise approved to practice in the jurisdiction in which the collection occurs;

(4) Is provided with detailed, clearly-illustrated, written instructions for collecting specimens in accordance with this subpart; and

(5) Performs collections in accordance with those instructions.

(d) Personnel available to testify at proceedings. The licensee or other entity shall ensure that qualified collection site personnel, when required, are available to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on non-negative alcohol, validity, or drug test results from specimens collected by or under contract to the licensee or other entity.

§26.87 Collection sites.

(a) Each FFD program must have one or more designated collection sites that have all necessary personnel, materials, equipment, facilities, and supervision to collect specimens for drug testing and to perform alcohol testing. Each collection site must provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a drug testing laboratory, and for the collection of oral fluids or breath specimens, and the security of alcohol testing devices and test results. A properly equipped mobile facility that meets the requirements of this part is an acceptable collection site.

(b) The collection site must provide for the donor's visual privacy while the donor and collector are viewing the results of an alcohol test, and for individual privacy while the donor is submitting a urine specimen, except if a directly observed urine specimen collection is required. Unauthorized personnel may not be present for the specimen collection.

(c) Contracts for collection site services must permit representatives of the NRC, licensee, or other entity to conduct unannounced inspections and audits and to obtain all information and documentation that is reasonably relevant to the inspections and audits.

(d) Licensees and other entities shall take the following measures to prevent unauthorized access to the collection site that could compromise the integrity of the collection process or the specimens.

(1) Unauthorized personnel may not be permitted in any part of the designated collection site where specimens are collected or stored;

(2) A designated collection site must be secure. If a collection site is dedicated solely to specimen collection, it must be secure at all times. Methods of assuring security may include,

but are not limited to, physical measures to control access, such as locked doors, alarms, or visual monitoring of the collection site when it is not occupied; and

(3) If a collection site cannot be dedicated solely to collecting specimens, the portion of the facility that is used for specimen collection must be secured and, during the time period during which a specimen is being collected, a sign must be posted to indicate that access is permitted only for authorized personnel.

(e) The following steps must be taken to deter the dilution and adulteration of urine specimens at the collection site:

(1) Agents that color any source of standing water in the stall or room in which the donor will provide a specimen, including, but not limited to, the toilet bowl or tank, must be placed in the source of standing water, so that the reservoirs of water are neither yellow nor colorless. Coloring agents may not interfere with drug or validity tests;

(2) There must be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs, or the source of water must be rendered unusable; and

(3) Chemicals or products that could be used to contaminate or otherwise alter the specimen must be removed from the collection site or secured. The collector shall inspect the enclosure in which urination will occur before each collection to ensure that no materials are available that could be used to subvert the testing process.

(f) In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement to collect a urine specimen, including, but not limited to, an event investigation, then the licensee or other entity may use a public rest room, on-site rest room, or hospital examining room according to the following procedures:

(1) The facility must be secured by visual inspection to ensure that no unauthorized persons are present, and that undetected access (e.g., through a rear door not in the view of the collector) is impossible. Security during the collection may be maintained by restricting access to collection materials and specimens. In the case of a public rest room, a sign must be posted or an individual assigned to ensure that no unauthorized personnel are present during the entire collection procedure to avoid embarrassment of the donor and distraction of the collector.

(2) If practical, a water coloring agent that meets the requirements of §26.87(e)(1) must be placed in the toilet bowl to be used by the donor and in any other accessible source of standing water, including, but not limited to, the toilet tank. The collector shall instruct the donor not to flush the toilet.

(3) A collector of the same gender as the donor shall accompany the donor into the area that will be used for specimen collection, but remain outside of the stall, if it is a multi-stalled rest room, or outside of the door to the room, if it is a single rest room, in which the donor will provide the specimen. If a collector of the same gender is not available, the collector shall select a same-gender person to accompany the donor. This person shall be instructed on the collection procedures specified in this subpart and his or her identity must be documented on the custody-and-control form.

(4) After the collector has possession of the specimen, the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt and shall then flush the toilet. The collector shall instruct the donor to participate with the collector in completing the chain-of-custody procedures.

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

specimen must remain under the direct control of an individual who is authorized by the licensee or other entity until the specimen is prepared for transfer, storage, or shipping in accordance with §26.117. The authorized individual shall be instructed on his or her responsibilities for maintaining custody and control of the specimen and his or her custody of the specimen must be documented on the custody-and-control form.

§26.89 Preparing to collect specimens for testing.

(a) When an individual has been notified of a requirement for testing and does not appear at the collection site within the time period specified by FFD program procedures, the collector shall inform FFD program management that the individual has not reported for testing. FFD program management shall ensure that the necessary steps are taken to determine whether the individual's undue tardiness or failure to appear for testing constitutes a violation of the licensee's or other entity's FFD policy. If FFD program management determines that the undue tardiness or failure to report for testing represents an attempt to subvert the testing process, the licensee or other entity shall impose on the individual the sanctions in §26.75(b). If FFD program management determines that the undue tardiness or failure to report does not represent a subversion attempt, the licensee or other entity may not impose sanctions but shall ensure that the individual is tested at the earliest reasonable and practical opportunity after locating the individual.

(b) Donors shall provide acceptable identification before testing.

(1) Acceptable identification includes photo-identification issued by a licensee or other entity who is subject to this part, or by the Federal, State, or local government. Licensees and other entities may not accept faxes or photocopies of identification.

(2) If the donor cannot produce acceptable identification before any testing that is required under this part other than pre-access testing, the collector shall proceed with the test and immediately inform FFD program management that the donor did not present acceptable identification. If the donor is scheduled for pre-access testing and cannot produce acceptable identification, the collector may not proceed with the collection, and shall inform FFD program management that the individual did not present acceptable identification. When so informed, FFD program management will take the necessary steps to determine whether the lack of identification was an attempt to subvert the testing process.

(3) The collector shall explain the testing procedure to the donor, show the donor the form(s) to be used, and ask the donor to sign a consent-to-testing form. The donor may not be required to list prescription medications or over-the-counter preparations that he or she has recently used.

(c) The collector shall inform the donor that, if the donor leaves the collection site before all of the collection procedures are completed or refuses to cooperate in the specimen collection process, it will be considered a refusal to test, and sanctions for subverting the testing process will be imposed in accordance with §26.75(b). If the donor fails to remain present through the completion of the collection procedures or refuses to cooperate in the collection procedures, the collector shall inform FFD program management to obtain guidance on the actions to be taken.

(d) In order to promote the security of specimens, avoid distraction of the collector, and ensure against any confusion in the identification of specimens, a collector shall conduct only one collection procedure at any given time. For this purpose, a urine collection procedure is complete when the urine specimen container has been sealed and initialed, the chain-of-custody form has been executed, and the donor has departed the collection site.

§26.91 Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use.

(a) Acceptable alcohol screening devices. Alcohol screening devices (ASDs), including devices that test specimens of oral fluids or breath, must be approved by the National Highway Traffic Safety Administration (NHTSA) and listed in the most current version of NHTSA's Conforming Products List (CPL) for such devices. An ASD that is listed in the NHTSA CPL may be used only for initial tests for alcohol, and may not be used for confirmatory tests.

(b) Acceptable evidential breath testing devices. Evidential breath testing devices (EBTs) listed in the NHTSA CPL for evidential devices that meet the requirements of paragraph (c) of this section must be used to conduct confirmatory alcohol tests, and may be used to conduct initial alcohol tests. Note that, among the devices listed in the CPL for EBTs, only those devices listed without an asterisk (*) may be used for confirmatory alcohol testing under this part.

(c) EBT capabilities. An EBT that is listed in the NHTSA CPL for evidential devices that has the following capabilities may be used for conducting initial alcohol tests and must be used for confirmatory alcohol tests under this part:

(1) Provides a printed result of each breath test;

(2) Assigns a unique number to each completed test, which the collector and donor can read before each test and which is printed on each copy of the test result;

(3) Prints, on each copy of the test result, the manufacturer's name for the device, its serial number, and the time of the test;

(4) Distinguishes alcohol from acetone at the 0.02 alcohol concentration level;

(5) Tests an air blank; and

(6) Performs an external calibration check.

(d) Quality assurance and quality control of ASDs.

(1) Licensees and other entities shall implement the most recent version of the quality assurance plan submitted to NHTSA for any ASD that is used for initial alcohol testing.

(2) Licensees and other entities may not use an ASD that fails the specified quality control checks or that has passed its expiration date.

(3) For ASDs that test breath specimens and meet EBT requirements for confirmatory testing, licensees and other entities shall also follow the device use and care requirements specified in paragraph (e) of this section.

(e) Quality assurance and quality control of EBTs.

(1) Licensees and other entities shall implement the most recent version of the manufacturer's instructions for the use and care of the EBT consistently with the quality assurance plan submitted to NHTSA for the EBT, including performing external calibration checks no less frequently than at the intervals specified in the manufacturer’s instructions.

(2) When conducting external calibration checks, licensees and other entities shall use only calibration devices appearing on NHTSA's CPL for “Calibrating Units for Breath Alcohol Tests.”

(3) If an EBT fails an external check of calibration, the licensee or other entity shall take the EBT out of service and cancel every positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed the last external calibration check. The EBT may not be used again for alcohol testing under this part until it is repaired and passes an external calibration check.

(4) Inspection, maintenance, and calibration of the EBT must be performed by its manufacturer or a maintenance representative certified either by the manufacturer or by a State health agency or other appropriate State agency.

§26.93 Preparing for alcohol testing.

(a) Immediately before collecting a specimen for alcohol testing, the collector shall —

(1) Ask the donor whether he or she, in the past 15 minutes, has had anything to eat or drink, belched, or put anything into his or her mouth (including, but not limited to, a cigarette, breath mint, or chewing gum), and instruct the donor that he or she should avoid these activities during the collection process;

(2) If the donor states that he or she has not engaged in the activities listed in paragraph (a)(1) of this section, alcohol testing may proceed;

(3) If the donor states that he or she has engaged in any of the activities listed in paragraph (a)(1) of this section, inform the donor that a 15-minute waiting period is necessary to prevent an accumulation of mouth alcohol from leading to an artificially high reading;

(4) Explain that it is to the donor's benefit to avoid the activities listed in paragraph (a)(1) of this section during the collection process;

(5) Explain that the initial and confirmatory tests, if a confirmatory test is necessary, will be conducted at the end of the waiting period, even if the donor has not followed the instructions; and

(6) Document that the instructions were communicated to the donor.

(b) With the exception of the 15-minute waiting period, if necessary, the collector shall begin for-cause alcohol and/or drug testing as soon as reasonably practical after the decision is

made that for-cause testing is required. When for-cause alcohol testing is required, alcohol testing may not be delayed by collecting a specimen for drug testing.

§26.95 Conducting an initial test for alcohol using a breath specimen.

(a) The collector shall perform the initial breath test as soon as practical after the donor indicates that he or she has not engaged in the activities listed in paragraph §26.93(a)(1) or after the 15-minute waiting period has elapsed, if required.

(b) To perform the initial test, the collector shall —

(1) Select, or allow the donor to select, an individually wrapped or sealed mouthpiece from the testing materials;

(2) Open the individually wrapped or sealed mouthpiece in view of the donor and insert it into the device in accordance with the manufacturer's instructions;

(3) Instruct the donor to blow steadily and forcefully into the mouthpiece for at least 6 seconds or until the device indicates that an adequate amount of breath has been obtained;

(4) Show the donor the displayed or printed test result; and

(5) Ensure that the test result record can be associated with the donor and is maintained secure.

(c) Unless problems in administering the breath test require an additional collection, only one breath specimen may be collected for the initial test. If an additional collection(s) is required, the collector shall rely upon the test result from the first successful collection to determine the need for confirmatory testing.

§26.97 Conducting an initial test for alcohol using a specimen of oral fluids.

(a) To perform the initial test, the collector shall —

(1) Check the expiration date on the device and show it to the donor (the device may not be used after its expiration date);

(2) Open an individually wrapped or sealed package containing the device in the presence of the donor;

(3) Offer the donor the choice of using the device or having the collector use it. If the donor chooses to use it, instruct the donor to insert the device into his or her mouth and use it in the manner described by the device's manufacturer;

(4) If the donor chooses not to use the device, or in all cases in which a new test is necessary because the device failed to activate, insert the device into the donor's mouth, and gather oral fluids in the manner described by the device's manufacturer (wear single-use examination or similar gloves while doing so and change them following each test); and

(5) When the device is removed from the donor's mouth, follow the manufacturer's instructions regarding necessary next steps to ensure that the device has activated.

(b) If the steps in paragraph (a) of this section could not be completed successfully (e.g., the device breaks, the device is dropped on the floor, the device fails to activate), the collector shall —

(1) Discard the device and conduct a new test using a new device. The new device must be one that has been under the collector's control before the test;

(2) Record the reason for the new test;

(3) Offer the donor the choice of using the device or having the collector use it unless the donor, in the opinion of the collector, was responsible for the new test needing to be

conducted. If the collector concludes that the donor was responsible, then the collector shall use the device to conduct the test; and

(4) Repeat the procedures in paragraph (a) of this section.

(c) If the second collection attempt in paragraph (b) of this section could not be completed, the collector shall —

(1) End the collection of oral fluids and document the reason(s) that the collection could not be completed; and

(2) Immediately conduct another initial test using an EBT.

(d) The collector shall read the result displayed on the device no sooner than the device's manufacturer instructs. In all cases, the collector shall read the result within 15 minutes of the test. The collector shall then show the device and its reading to the donor, record the result, and record that an ASD was used.

(e) Devices, swabs, gloves, and other materials used in collecting oral fluids may not be re-used.

§26.99 Determining the need for a confirmatory test for alcohol.

(a) If the initial test result is less than 0.02 percent BAC, the collector shall declare the test result as negative.

(b) If the initial test result is 0.02 percent BAC or higher, the collector shall ensure that the time at which the test was concluded (i.e., the time at which the test result was known) is recorded and inform the donor that a confirmatory test for alcohol is required.

§26.101 Conducting a confirmatory test for alcohol.

(a) The confirmatory test must begin as soon as possible, but no more than 30 minutes after the conclusion of the initial test.

(b) To complete the confirmatory test, the collector shall —

(1) In the presence of the donor, conduct an air blank on the EBT before beginning the confirmatory test and show the result to the donor;

(2) Verify that the reading is 0.00. If the reading is 0.00, the test may proceed. If not, then conduct another air blank;

(3) If the reading on the second air blank is 0.00, the test may proceed. If the reading is greater than 0.00, take the EBT out of service and proceed with the test using another EBT. If an EBT is taken out of service for this reason, the EBT may not be used for further testing until it is found to be within tolerance limits on an external check of calibration;

(4) Open an individually wrapped or sealed mouthpiece in view of the donor and insert it into the device in accordance with the manufacturer's instructions;

(5) Read the unique test number displayed on the EBT, and ensure that the donor reads the same number;

(6) Instruct the donor to blow steadily and forcefully into the mouthpiece for at least 6 seconds or until the device indicates that an adequate amount of breath has been obtained; and

(7) Show the donor the result displayed on or printed by the EBT, record the result, and document the time at which the confirmatory test result was known.

(c) Unless there are problems in administering the breath test that require an additional collection, the collector shall collect only one breath specimen for the confirmatory test. If an

additional collection(s) is required because of problems in administering the breath test, the collector shall rely upon the breath specimen from the first successful collection to determine the confirmatory test result. Collection procedures may not require collectors to calculate an average or otherwise combine results from two or more breath specimens to determine the confirmatory test result.

(d) If an EBT that meets the requirements of §26.91(b) and (c) was used for the initial alcohol test, the same EBT may be used for confirmatory testing.

§26.103 Determining a confirmed positive test result for alcohol.

(a) A confirmed positive test result for alcohol must be declared under any of the following conditions:

(1) When the result of the confirmatory test for alcohol is 0.04 percent BAC or higher;

(2) When the result of the confirmatory test for alcohol is 0.03 percent BAC or higher and the donor had been in a work status for at least 1 hour at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.); or

(3) When the result of the confirmatory test for alcohol is 0.02 percent BAC or higher and the donor had been in a work status for at least 2 hours at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.).

(b) When the result of the confirmatory test for alcohol is equal to or greater than 0.01 percent BAC but less than 0.02 percent BAC and the donor has been in a work status for 3 hours or more at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.), the collector shall declare the test result as negative and inform FFD program management. The licensee or other entity shall prohibit the donor from

performing any duties that require him or her to be subject to this part and may not return the individual to performing such duties until a determination of fitness indicates that the donor is fit to safely and competently perform his or her duties.

§26.105 Preparing for urine collection.

(a) The collector shall ask the donor to remove any unnecessary outer garments, such as a coat or jacket, which might conceal items or substances that the donor could use to tamper with or adulterate his or her urine specimen. The collector shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room or stall in which the urine specimen is collected. The donor may retain his or her wallet.

(b) The collector shall also ask the donor to empty his or her pockets and display the items in them to enable the collector to identify items that the donor could use to adulterate or substitute his or her urine specimen. The donor shall permit the collector to make this observation. If the donor refuses to show the collector the items in his or her pockets, this is considered a refusal to test. If an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen, the collector shall contact the MRO or FFD program manager to determine whether a directly observed collection is required. If the item appears to have been inadvertently brought to the collection site, the collector shall secure the item and continue with the normal collection procedure. If the collector identifies nothing that the donor could use to adulterate or substitute the specimen, the donor may place the items back into his or her pockets.

(c) The collector shall instruct the donor to wash and dry his or her hands before urinating.

(d) After washing his or her hands, the donor shall remain in the presence of the collector and may not have access to any water fountain, faucet, soap dispenser, cleaning agent, or other materials that he or she could use to adulterate the urine specimen.

(e) The collector may select, or allow the donor to select, an individually wrapped or sealed collection container from the collection kit materials. Either the collector or the donor, with both present, shall unwrap or break the seal of the collection container. With the exception of the collection container, the donor may not take anything from the collection kit into the room or stall used for urination.

§26.107 Collecting a urine specimen.

(a) The collector shall direct the donor to go into the room or stall used for urination, provide a specimen of the quantity that has been predetermined by the licensee or other entity, as defined in §26.109(a), not flush the toilet, and return with the specimen as soon as the donor has completed the void.

(1) The donor shall provide his or her urine specimen in the privacy of a room, stall, or otherwise partitioned area (private area) that allows for individual privacy, except if a directly observed collection is required, as described in §26.115;

(2) Except in the case of a directly observed collection, no one may go with the donor into the room or stall in which the donor will provide his or her specimen; and

(3) The collector may set a reasonable time limit for voiding.

(b) The collector shall pay careful attention to the donor during the entire collection process to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine is in plain view or an attempt to bring an adulterant or urine substitute into the

private area used for urination). If any such conduct is detected, the collector shall document the conduct on the custody-and-control form and contact FFD program management to determine whether a directly observed collection is required, as described in §26.115.

(c) After the donor has provided the urine specimen and submitted it to the collector, the donor shall be permitted to wash his or her hands. The collector shall inspect the toilet bowl and room or stall in which the donor voided to identify any evidence of a subversion attempt, and then flush the toilet.

§26.109 Urine specimen quantity.

(a) Licensees and other entities who are subject to this part shall establish a predetermined quantity of urine that donors are requested to provide when submitting a specimen. At a minimum, the predetermined quantity must include 30 milliliters (mL) to ensure that a sufficient quantity of urine is available for initial and confirmatory validity and drug tests at an HHS-certified laboratory, and for retesting of an aliquot of the specimen if requested by the donor in accordance with §26.165(b). The licensee's or other entity's predetermined quantity may include more than 30 mL, if the testing program follows split specimen procedures, tests for additional drugs, or performs initial testing at a licensee testing facility. Where collected specimens are to be split under the provisions of this part, the predetermined quantity must include an additional 15 mL.

(b) If the quantity of urine in the first specimen provided by the donor is less than 30 mL, the collector shall take the following steps:

(1) The collector shall encourage the donor to drink a reasonable amount of liquid (normally, 8 ounces of water every 30 minutes, but not to exceed a maximum of 24 oz. over 3

hours) until the donor provides a specimen containing at least 30 mL. The collector shall provide the donor with a separate collection container for each successive specimen;

(2) Once the donor provides a specimen of at least 30 mL, the collection must end. If the specimen is at least 30 mL but is less than the licensee's or other entity's predetermined quantity, the licensee or other entity may not require the donor to provide additional specimens and may not impose any sanctions on the donor. If the donor provides a specimen of 30 mL or more, but the specimen is less than the predetermined quantity, the collector shall forward the specimen to the HHS-certified laboratory for testing. If the donor provides a specimen of at least the predetermined quantity, the specimen may be processed in accordance with the FFD program's usual testing procedures;

(3) If the donor has not provided a specimen of at least 30 mL within 3 hours of the first unsuccessful attempt to provide a specimen of the predetermined quantity, the collector shall discontinue the collection and notify the FFD program manager or MRO to initiate the "shy bladder" procedures in §26.119; and

(4) Neither the donor nor the collector may combine specimens. The collector shall discard specimens of less than 30 mL, except if there is reason to believe that the donor has diluted, adulterated, substituted, or otherwise tampered with the specimen, based upon the collector's observations of the donor's behavior during the collection process or the specimen's characteristics, as specified in §26.111. If the collector has a reason to believe that a specimen that is 15 mL or more, but less than 30 mL, has been diluted, adulterated, substituted, or altered, the collector shall prepare the suspect specimen for shipping to the HHS-certified laboratory and contact FFD program management to determine whether a directly observed collection is required, as described in §26.115.

§26.111 Checking the validity of the urine specimen.

(a) Immediately after the donor provides the urine specimen to the collector, including specimens of less than 30 mL but greater than 15 mL, the collector shall measure the temperature of the specimen. The temperature-measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement may not exceed 4 minutes, and may need to be less if the ambient temperature is low or the specimen quantity is less than 30 mL.

(b) If the temperature of a urine specimen is outside the range of 90 ºF to 100 ºF, the collector shall inform the donor that he or she may volunteer to have his or her temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen.

(c) Immediately after the donor provides a urine specimen, including specimens of less than 30 mL but greater than 15 mL, the collector shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. The collector shall note any unusual findings on the custody-and-control form.

(d) If there is reason to believe that the donor may have attempted to dilute, substitute, or adulterate the specimen based upon specimen temperature or other observations made during the collection, the collector shall contact the designated FFD program manager, who may consult with the MRO, to determine whether the donor has attempted to subvert the testing process or whether other circumstances may explain the observations. The FFD program manager or MRO may require the donor to provide a second specimen as soon as possible, including under direct observation.

(e) Any specimen of 15 mL or more that the collector suspects has been diluted, substituted, or adulterated must be sent directly to the HHS-certified laboratory for initial and

confirmatory testing, if required, and may not be subject to initial testing at a licensee testing facility.

(f) As much of the suspect specimen as possible must be preserved.

(g) An acceptable specimen is free of any apparent contaminants, meets the required basic quantity of at least 30 mL, and is within the acceptable temperature range.

§26.113 Splitting the urine specimen.

(a) Licensees and other entities who are subject to this part may, but are not required to, use split-specimen methods of collection.

(b) If the urine specimen is to be split into two specimen bottles, hereinafter referred to as Bottle A and Bottle B, the collector shall take the following steps:

(1) The collector shall instruct the donor to urinate into either a specimen bottle or a specimen container;

(2) The collector, in the presence of the donor and after determining specimen temperature as described in §26.111(a), shall split the urine specimen. Bottle A must contain a minimum of 30 mL of urine and Bottle B must contain 15 mL. The Bottle A specimen must be used for drug and validity testing at the HHS-certified laboratory. If there is less than 15 mL of urine available for Bottle B, the specimen in Bottle A must nevertheless be processed for testing; and

(3) The collector shall ask the donor to observe the splitting of the urine specimen and to maintain visual contact with both specimen bottles until the custody-and-control form(s) for both specimens are completed, the specimens are sealed, and the specimens and form(s) are prepared for secure storage or shipping.

(c) Licensees and other entities may use aliquots of the specimen collected for validity screening and initial validity and drug testing at the licensee testing facility, as permitted under §26.31(d)(3)(ii), or to test for additional drugs, as permitted under §26.31(d)(1)(i)(A), but only if sufficient urine is available for such testing after the specimen has been split into Bottle A and Bottle B.

§26.115 Collecting a urine specimen under direct observation.

(a) Procedures for collecting urine specimens must provide for the donor's privacy unless directed by this part or the MRO or FFD program manager determines that a directly observed collection is warranted. The following circumstances constitute the exclusive grounds for performing a directly observed collection:

(1) The donor has presented, at this or a previous collection, a urine specimen that the HHS-certified laboratory reported as being substituted, adulterated, or invalid to the MRO and the MRO reported to the licensee or other entity that there is no adequate medical explanation for the result;

(2) The donor has presented, at this collection, a urine specimen that falls outside the required temperature range, and

(i) Either the donor declines to provide a measurement of body temperature; or

(ii) The donor's measured body temperature varies by more than 1EC/1.8EF from the temperature of the specimen;

(3) The collector observes conduct clearly and unequivocally indicating an attempt to dilute, substitute, or adulterate the specimen; and

(4) A directly observed collection is required under §26.69.

(b) Before collecting a urine specimen under direct observation, the collector shall obtain the agreement of the FFD program manager or MRO to obtain a urine specimen under direct observation. After obtaining agreement, the collector shall ensure that a specimen is collected under direct observation as soon as reasonably practicable.

(c) The collector shall explain to the donor the reason for direct observation of the collection under paragraph (a) of this section.

(d) The collector shall complete a new custody-and-control form for the specimen that is obtained from the directly observed collection. The collector shall record that the collection was observed and the reason(s) for the directly observed collection on the form.

(e) The collector shall ensure that the observer is the same gender as the individual. A person of the opposite gender may not act as the observer under any conditions. The observer may be a different person from the collector and need not be a qualified collector.

(f) If someone other than the collector is to observe the collection, the collector shall verbally instruct the observer to follow the procedures in this paragraph. The individual who observes the collection shall follow these procedures:

(1) The observer shall instruct the donor to adjust his or her clothing to ensure that the area of the donor's body between the waist and knees is exposed;

(2) The observer shall watch the donor urinate into the collection container. Specifically, the observer shall watch the urine go from the donor's body into the collection container;

(3) If the observer is not the collector, the observer may not take the collection container from the donor, but shall observe the specimen as the donor takes it to the collector; and

(4) If the observer is not the collector, the collector shall record the observer's name on the custody-and-control form.

(g) If a donor declines to allow a directly observed collection that is required or permitted under this section, this constitutes a refusal to test.

(h) If a collector learns that a directly observed collection should have been performed but was not, the collector shall inform the FFD program manager, or his or her designee. The FFD program manager or designee shall ensure that a directly observed collection is immediately performed.

§26.117 Preparing urine specimens for storage and shipping.

(a) Both the donor and the collector shall keep the donor's urine specimen(s) in view at all times before the specimen(s) are sealed and labeled. If any specimen or aliquot is transferred to another container, the collector shall ask the donor to observe the transfer and sealing of the container with a tamper-evident seal.

(b) Both the collector and the donor shall be present (at the same time) during the procedures outlined in this section.

(c) The collector shall place an identification label securely on each container. The label must contain the date, the donor's specimen number, and any other identifying information provided or required by the FFD program. The collector shall also apply a tamper-evident seal on each container if it is separate from the label. The specimen bottle must be securely sealed to prevent undetected tampering.

(d) The donor shall initial the identification label(s) on the specimen bottle(s) for the purpose of certifying that the specimen was collected from him or her. The collector shall also ask the donor to read and sign a statement on the custody-and-control form certifying that the

specimen(s) identified as having been collected from the donor is, in fact, the specimen(s) that he or she provided.

(e) The collector shall complete the custody-and-control form(s) and shall certify proper completion of the collection.

(f) The specimens and chain-of-custody forms must be packaged for transfer to the HHS-certified laboratory or the licensee's testing facility. If the specimens are not immediately prepared for transfer, they must be appropriately safeguarded during temporary storage.

(g) While any part of the chain-of-custody procedures is being performed, the specimens and custody documents must be under the control of the involved collector. The collector may not leave the collection site during the interval between presentation of the specimen by the donor and securing of the specimens with identifying labels bearing the donor’s specimen identification numbers and seals initialed by the donor. If the involved collector momentarily leaves his or her workstation, the sealed specimens and custody-and-control forms must be secured or taken with him or her. If the collector is leaving for an extended period of time, the specimens must be packaged for transfer to the HHS-certified laboratory or the licensee testing facility and secured before the collector leaves the collection site.

(h) The specimen(s) sealed in a shipping container must be immediately transferred, appropriately safeguarded during temporary storage, or kept under the personal control of an authorized individual until transferred. These minimum procedures apply to the transfer of specimens to licensee testing facilities from collection sites (except where co-located) as well as to the shipping of specimens to HHS-certified laboratories. As an option, licensees and other entities may ship several specimens via courier in a locked or sealed shipping container.

(i) Collection site personnel shall ensure that a custody-and-control form is packaged with its associated urine specimen bottle. Unless a collection site and a licensee testing facility are co-located, the sealed and labeled specimen bottles, with their associated custody-and-control forms that are being transferred from the collection site to the drug testing laboratory must be placed in a second, tamper-evident shipping container. The second container must be designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, shipping bags, padded mailers, or bulk insulated shipping containers with that capability), so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal.

(j) Collection site personnel shall arrange to transfer the collected specimens to the HHS-certified laboratory or the licensee testing facility. Licensees and other entities shall take appropriate and prudent actions to minimize false negative results from specimen degradation. Specimens that have not been shipped to the HHS-certified laboratory or the licensee testing facility within 24 hours of collection and any specimen that is suspected of having been substituted, adulterated, or tampered with in any way must be maintained cooled to not more than 6 °C (42.8 °F) until they are shipped to the HHS-certified laboratory. Specimens must be shipped from the collection site to the HHS-certified laboratory or the licensee testing facility as soon as reasonably practical but, except under unusual circumstances, the time between specimen shipment and receipt of the specimen at the licensee testing facility or HHS-certified laboratory should not exceed 2 business days.

(k) Couriers, express carriers, and postal service personnel do not have direct access to the custody-and-control forms or the specimen bottles. Therefore, there is no requirement that such personnel document chain of custody on the custody-and-control forms during transit.

Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service.

§26.119 Determining "shy" bladder.

(a) When a donor has not provided a specimen of at least 30 mL within the 3 hours permitted for urine collection, FFD program personnel shall direct the donor to obtain, within 5 business days, an evaluation from a licensed physician who is acceptable to the MRO and has expertise in the medical issues raised by the donor's failure to provide a sufficient specimen. The MRO may perform this evaluation if the MRO has the appropriate expertise.

(b) If another physician will perform the evaluation, the MRO shall provide the other physician with the following information and instructions:

(1) The donor was required to take a drug test, but was unable to provide a sufficient quantity of urine to complete the test;

(2) The potential consequences of refusing to take the required drug test; and

(3) The physician must agree to follow the requirements of paragraphs (c) through (f) of this section.

(c) The physician who conducts this evaluation shall make one of the following determinations:

(1) A medical condition has, or with a high degree of probability could have, precluded the donor from providing a sufficient amount of urine; or

(2) There is an inadequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the donor from providing a sufficient quantity of urine.

(d) For purposes of this section, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of “situational anxiety” or dehydration.

(e) The physician who conducts this evaluation shall provide a written statement of his or her determination and the basis for it to the MRO. This statement may not include detailed information on the donor's medical condition beyond what is necessary to explain the determination.

(f) If the physician who conducts this evaluation determines that the donor’s medical condition is a serious and permanent or long-term disability that is highly likely to prevent the donor from providing a sufficient amount of urine for a very long or indefinite period of time, the physician shall set forth this determination and the reasons for it in the written statement to the MRO.

(g) The MRO shall seriously consider and assess the information provided by the physician in deciding whether the donor has a medical condition that has, or with a high degree of probability could have, precluded the donor from providing a sufficient amount of urine, as follows:

(1) If the MRO concurs with the physician’s determination, then the MRO shall declare that the donor has not violated the FFD policy and the licensee or other entity shall take no further action with respect to the donor;

(2) If the MRO determines that the medical condition has not, or with a high degree of probability could not have, precluded the donor from providing a sufficient amount of urine, then the MRO shall declare that there has been a refusal to test; or

(3) If the MRO determines that the medical condition is highly likely to prevent the donor from providing a sufficient amount of urine for a very long or indefinite period of time, then the MRO shall authorize an alternative evaluation process, tailored to the individual case, for drug testing.

Subpart F – Licensee Testing Facilities

§26.121 Purpose.

This subpart contains requirements for facilities that are operated by licensees and other entities who are subject to this part to perform initial tests of urine specimens for validity, drugs, and drug metabolites.

§26.123 Testing facility capabilities.

Each licensee testing facility shall have the capability, at the same premises, to perform either validity screening tests or initial validity tests or both, and initial drug tests for each drug and drug metabolite for which testing is conducted.

§26.125 Licensee testing facility personnel.

(a) Each licensee testing facility shall have one or more individuals who are responsible for day-to-day operations and supervision of the testing technicians. The designated individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or equivalent. He or she shall also have training and experience in the theory and practice of the procedures used in the licensee testing facility, and a thorough

understanding of quality control practices and procedures, the review, interpretation, and reporting of test results, and proper remedial actions to be taken in response to detection of abnormal test or quality control results.

(b) Other technicians or non-technical staff shall have the necessary training and skills for their assigned tasks. Technicians who perform urine specimen testing shall have documented proficiency in operating the testing instruments and devices used at the licensee testing facility.

(c) Licensee testing facility personnel files must include each individual's resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests that establish employee competency for the position he or she holds; and appropriate data to support determinations of honesty and integrity conducted in accordance with this part.

§26.127 Procedures.

(a) Licensee testing facilities shall develop, implement, and maintain clear and well-documented procedures for accession, shipment, and testing of urine specimens.

(b) Written chain-of-custody procedures must describe the methods to be used to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to the HHS-certified laboratory, and continuing until final disposition of the specimens.

(c) Licensee testing facilities shall develop, implement, and maintain written standard operating procedures for each assay performed for drug and specimen validity testing. If a licensee testing facility performs validity screening tests with non-instrumented devices, the

licensee testing facility shall develop, implement, and maintain written standard operating procedures for each device. The procedures must include, but are not limited to, detailed descriptions of —

(1) The principles of each test;

(2) Preparation of reagents, standards, and controls;

(3) Calibration procedures;

(4) Derivation of results;

(5) Linearity of the methods;

(6) Sensitivity of the methods;

(7) Cutoff values;

(8) Mechanisms for reporting results;

(9) Controls;

(10) Criteria for unacceptable specimens and results;

(11) Reagents and expiration dates; and

(12) References.

(d) Licensee testing facilities shall develop, implement, and maintain written procedures for instrument and device setup and normal operation, including the following:

(1) A schedule for checking critical operating characteristics for all instruments and devices;

(2) Tolerance limits for acceptable function checks; and

(3) Instructions for major troubleshooting and repair.

(e) Licensee testing facilities shall develop, implement, and maintain written procedures for remedial actions to be taken when systems and non-instrumented testing devices (if used for validity screening tests) are out of acceptable limits or errors are detected. Each facility shall maintain documentation that these procedures are followed and that all necessary corrective actions are taken. In addition, each facility shall have systems in place to verify all stages of testing and reporting and to document the verification.

§26.129 Assuring specimen security, chain of custody, and preservation.

(a) Each licensee testing facility shall be secure at all times. Each facility shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the licensee testing facility's processes or areas where records are stored. Access to these secured areas must be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times while in the licensee testing facility.

(b) When specimens are received, licensee testing facility personnel shall inspect each package for evidence of possible tampering and shall compare information on specimen containers within each package to the information on the accompanying custody-and-control forms. Licensee testing facility personnel shall attempt to resolve any discrepancies identified in the information on specimen bottles or on the accompanying custody-and-control forms. Indications of tampering with specimens in transit from the collection site, or at a licensee testing facility, must be reported to senior licensee or other entity management as soon as practical and no later than 8 hours after the indications are identified. In response to such reports, licensee or other entity management personnel shall initiate an investigation to

determine whether tampering has occurred. If the investigation determines that tampering has occurred, licensee or other entity management shall ensure that corrective actions are taken. If there is reason to believe that the integrity or identity of a specimen is in question (as a result of tampering or discrepancies between the information on specimen bottle and on the accompanying custody-and-control forms that cannot be resolved), the specimen may not be tested and the licensee or other entity shall ensure that another collection occurs as soon as reasonably practical.

(c) The licensee testing facility shall retain specimen containers within the testing facility's accession area until all analyses have been completed. Testing facility personnel shall use aliquots of the specimen and licensee testing facility chain-of-custody forms, or other appropriate methods of tracking aliquot custody and control, when conducting validity screening and initial validity and drug tests. The original specimen bottles and the original custody-and-control forms must remain in secure storage. Licensee testing facility personnel may discard specimens and aliquots as soon as practical after validity screening or initial validity tests have demonstrated that the specimen appears valid and initial test results for drugs and drug metabolites are negative.

(d) The licensee testing facility’s procedure for tracking custody and control of specimens and aliquots must protect the identity of the donor, and provide documentation of the testing process and transfers of custody of the specimen and aliquots. Each time a specimen or aliquot is handled or transferred within the licensee testing facility, testing facility personnel shall document the date and purpose and every individual in the chain of custody must be identified.

(e) Urine specimens identified as non-negative at a licensee testing facility must be shipped to an HHS-certified laboratory for testing as soon as reasonably practical.

(f) Licensee testing facility personnel shall take appropriate and prudent actions to minimize false negative results from specimen degradation. If validity screening, initial validity, or initial drug test results are non-negative or if a specimen has not been tested within 24 hours of receipt at the licensee testing facility, then the facility shall maintain the specimen cooled to not more than 6 °C (42.8 °F) until it is forwarded to the HHS-certified laboratory for further testing, if required. Split specimens in Bottle B that are associated with non-negative specimens in Bottle A must also be maintained cooled (as previously specified) until test results from the HHS-certified laboratory are known to be negative for Bottle A; until the MRO informs the licensee testing facility that Bottle B must be forwarded to an HHS-certified laboratory for testing; or until the specimen is moved to long-term, frozen storage, in accordance with §26.135(c).

(g) Licensee testing facility personnel shall ensure that the original custody-and-control form is packaged with its associated urine specimen bottle. Sealed and labeled specimen bottles, with their associated custody-and-control forms, being transferred from the licensee testing facility to the HHS-certified laboratory must be placed in a second, tamper-evident shipping container 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.

(h) Couriers, express carriers, and postal service personnel do not have direct access to the custody-and-control forms or the specimen bottles. Therefore, such personnel are not required to document chain of custody on the custody-and-control forms during transit. Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service.

§26.131 Cutoff levels for validity screening and initial validity tests.

(a) Each validity test result from the licensee testing facility must be based on performing either a validity screening test or an initial validity test, or both, on one or more aliquots of a urine specimen. The licensee testing facility shall forward any specimen that yields a non-negative validity screening or initial validity test result to the HHS-certified laboratory for further testing. Licensee testing facilities need not perform validity screening tests before conducting initial validity tests of a specimen.

(b) At a minimum, the licensee testing facility shall test each urine specimen for creatinine, pH, and one or more oxidizing adulterants. Licensees and other entities may not specify more stringent cutoff levels for validity screening and initial validity tests than those specified in this section. If tests or observations indicate one or more of the following from either a validity screening test or an initial validity test, the licensee testing facility shall forward the specimen to the HHS-certified laboratory for additional testing:

(1) Creatinine is less than 20 milligrams (mg) per deciliter (dL);

(2) Using either a colorimetric pH test or pH meter, the pH of the specimen meets either of the following criteria:

(i) pH less than 3, or

(ii) pH equal to or greater than 9.

(3) Nitrite concentration is equal to or greater than 500 micrograms (mcg) per milliliter (mL) using either a nitrite colorimetric test or a general oxidant colorimetric test;

(4) Presence of chromium (VI) is indicated using either a general oxidant colorimetric test (with a cutoff equal to or greater than 50 mcg/mL chromium (VI) equivalents) or a

chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL);

(5) Presence of halogen (e.g., bleach, iodine, fluoride) is indicated using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite equivalents or equal to or greater than 50 mcg/mL chromium (VI) equivalents) or a halogen colorimetric test (halogen concentration equal to or greater than the LOD);

(6) Presence of glutaraldehyde is indicated using either an aldehyde test (aldehyde present) or the characteristic immunoassay response is observed on one or more drug immunoassay tests;

(7) Presence of pyridine (pyridinium chlorochromate) is indicated using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite equivalents or equal to or greater than 50 mcg/mL chromium (VI) equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL);

(8) Presence of a surfactant is indicated by using a surfactant colorimetric test with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate equivalent ; or

(9) The specimen shows evidence of adulterants, including, but not limited to, the following:

(i) Abnormal physical characteristics;

(ii) Reactions or responses characteristic of an adulterant obtained during the initial test; or

(iii) A possible unidentified interfering substance or adulterant, demonstrated by interference occurring on the immunoassay drug tests on separate aliquots (i.e., valid immunoassay drug test results cannot be obtained).

§26.133 Cutoff levels for drugs and drug metabolites.

Subject to the provisions of §26.31(d)(3)(iii), licensees and other entities may specify more stringent cutoff levels for drugs and drug metabolites than those in the table below and, in such cases, may report initial test results for only the more stringent cutoff levels. Otherwise, the following cutoff levels must be used for initial testing of urine specimens to determine whether they are negative for the indicated drugs and drug metabolites:

Initial test cutoff levels for drugs and drug metabolites

Drug or Metabolites	Cutoff level (ng/mL)
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	2,000
Phencyclidine	25
Amphetamines	1,000

§26.135 Split specimens.

(a) If the FFD program follows split-specimen procedures, as described in §26.113, the licensee testing facility shall analyze aliquots of the specimen for the licensee's or other entity's purposes as described in this part. Except as provided in paragraph (b) in this section, the licensee testing facility shall store Bottles A and B of the specimen in a secure manner until the facility has finished testing. If the initial validity and drug test results are negative and the specimen in Bottle A will not be forwarded to the HHS-certified laboratory, the licensee testing facility may discard both Bottle A and B. If any test results are non-negative, the licensee

testing facility shall forward Bottle A to the HHS-certified laboratory for testing and shall retain Bottle B in secure storage or may forward it to the HHS-certified laboratory for storage.

(b) Within 3 business days (Monday through Friday, excluding holidays) of being notified by the MRO that the HHS-laboratory reported that donor's specimen yielded a non-negative test result, the donor may request that the split specimen in Bottle B be tested by another HHS-certified laboratory. The MRO shall inform the donor of this option, and the specimen in Bottle B may be tested only at the request of donor. When requested, the licensee or other entity shall ensure that Bottle B is forwarded to an HHS-certified laboratory other than the laboratory that tested the specimen in Bottle A as soon as practical, and not later than one business day following the day of the donor's request to have Bottle B tested. The donor shall provide his or her written permission for the testing of Bottle B and neither the licensee, MRO, NRC, nor any other entity may order testing of Bottle B without the donor's written permission.

(c) If the MRO confirms that the specimen in Bottle A is non-negative and the donor does not request that Bottle B be tested, the licensee or other entity shall ensure that Bottle B is maintained in long-term, frozen storage (-20 ºC or less) for a minimum of 1 year. After the end of 1 year, the licensee or other entity may discard Bottle B, with the exception that the licensee testing facility shall retain any specimens under legal challenge, or as requested by the NRC, until the specimen is no longer needed.

§26.137 Quality assurance and quality control.

(a) Quality assurance program. Each licensee testing facility shall have a quality assurance program that encompasses all aspects of the testing process including, but not limited to, specimen acquisition, chain of custody, security, reporting of results, validity screening (if validity screening tests are performed), initial validity and drug 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 validity testing and testing for drugs and drug metabolites.

(b) Performance testing and quality control requirements for validity screening tests.

(1) Licensee testing facilities may rely upon non-instrumented devices to perform validity screening tests to determine the need for initial tests of specimen validity. Licensee testing facilities shall use only non-instrumented devices to perform validity screening tests that meet the following criteria:

(i) Either the device has been cleared by the U.S. Food and Drug Administration and placed upon the SAMHSA list of point-of-collection testing devices that are certified for use in the Federal Workplace Drug Testing Program in the Federal Register; or

(ii) Before using the device, the licensee or other entity has ensured that the device effectively determines the validity of a specimen, as demonstrated by documentation that the device meets the following performance testing requirements:

(A) A total of 100 devices in representative numbers from all currently available manufactured lots of the device have been performance tested by the licensee testing facility or an HHS-certified laboratory following the manufacturer-specified testing procedures;

(B) The performance testing samples used to test the 100 devices included samples with a nitrite concentration in the ranges of 650 mcg/mL–800 mcg/mL or 250 mcg/mL–400 mcg/mL; a creatinine concentration in the ranges of 5 mg/dL–20 mg/dL or 1 mg/dL–5 mg/dL; and pH in the ranges of 1–3 or 10–12; and

(C) Test results from the performance testing required in this paragraph show that the device correctly identified at least 80 percent of the total validity test challenges or correctly

identified at least 80 percent of the challenges for a specific validity test, and did not report any sample as adulterated with a compound that was not present in the sample.

(iii) After the licensee testing facility has placed the device in service, the licensee or other entity shall verify either that the device remains on the SAMHSA-certified list, or that the device continues to effectively determine the validity of a specimen by conducting, or requesting the HHS-certified laboratory to conduct performance testing of 50 of the devices in representative numbers from all currently available manufactured lots of the device in accordance with the criteria specified in paragraphs (b)(1)(ii)(A) through (b)(1)(ii)(C) of this section. This performance testing must be performed at a nominal annual frequency.

(iv) In addition, the licensee or other entity shall ensure that the manufacturer informs the licensee or other entity of any design changes or alterations made to the device. If so informed, the licensee or other entity shall consult with the MRO or the HHS-certified laboratory to determine whether additional performance testing is required to ensure that the modified device continues to be effective. If the MRO or HHS-certified laboratory recommends additional performance testing, the licensee or other entity shall ensure that it is completed in accordance with paragraph (b)(1)(iii) of this section.

(2) At the beginning of any 8-hour period during which the licensee testing facility will perform validity screening tests, licensee testing facility personnel shall test a minimum of 1 quality control sample that is negative for each specific validity test to be performed (e.g., nitrites, chromium) during the 8-hour period, and 1 quality control sample that is non-negative for the specific validity test to be performed during the 8-hour period. The results of these tests must be correct before any donor specimens may be tested. If correct results are not obtained (i.e., the device provided either false positive or false negative results), the licensee testing facility shall immediately stop using the device and conduct the investigation required in

paragraph (f) of this section. If the incorrect result is a false negative result, licensees and other entities shall notify the NRC in accordance with §26.219(c)(3).

(3) The licensee testing facility shall also submit at least 1 specimen out of every 10 specimens that test negative using the non-instrumented validity screening device to an HHS-certified laboratory as part of the licensee testing facility's quality assurance program. If results from the HHS-certified laboratory indicate that a device failed to perform correctly (i.e., provided either false positive or false negative results), the licensee or other entity shall immediately stop using the device and conduct the investigation required in paragraph (f) of this section. If the incorrect result is a false negative result, licensees and other entities shall notify the NRC in accordance with §26.219(c)(3).

(4) Validity screening tests must measure a specimen's creatinine concentration to 1 decimal place.

(5) Dipsticks, colorimetric pH tests that have a narrow dynamic range and do not support the 2–12 pH cutoffs, and pH paper may be used only for validity screening tests to determine whether initial validity tests must be performed. The pH screening tests must have, at a minimum, the following controls:

(i) One control below the lower decision point in use;

(ii) One control between the decision points in use; and

(iii) One control above the upper decision point in use.

(6) Licensee testing facilities may use either a general oxidizing adulterant test or one or more specific oxidizing adulterant tests for validity screening tests. When a general oxidizing adulterant test is used, the test must be able to detect at least the activity equivalent of 500 mcg/mL of nitrite. Dipsticks that meet the performance testing requirements in paragraph (b)(1)

through (b)(3) of this section may be used to determine the presence of nitrite or other oxidizing adulterants at a concentration sufficient to require initial validity testing.

(c) Non-negative validity screening test results. If the results of a validity screening test indicate that the specimen may be adulterated, substituted, dilute, or invalid, the licensee testing facility may either perform initial validity testing or shall forward the specimen to the HHS-certified laboratory for further testing.

(d) Quality control requirements for performing initial validity tests.

(1) Creatinine. Creatinine concentration must be measured to 1 decimal place. The initial creatinine test must have a control in the range of 3–20 mg/dL and a control in the range of 21–25 mg/dL.

(2) Requirements for performing initial pH tests are as follows:

(i) Colorimetric pH tests that have a dynamic range of 2–12 and pH meters must be capable of measuring pH to 1 decimal place.

(ii) An initial colorimetric pH test must have the following calibrators and controls:

(A) One calibrator at 3;

(B) One calibrator at 11;

(C) One control in the range of 2–2.8;

(D) One control in the range 3.2–4;

(E) One control in the range of 4.5–9;

(F) One control in the range of 10–10.8; and

(G) One control in the range of 11.2–12.

(iii) If a pH screening test is not used, an initial pH meter test must have the following calibrators and controls:

(A) One calibrator at 4;

(B) One calibrator at 7;

(C) One calibrator at 10;

(D) One control in the range of 2–2.8;

(E) One control in the range 3.2– 4;

(F) One control in the range of 10–10.8; and

(G) One control in the range of 11.2–12.

(iv) If a pH screening test is used, an initial pH meter test must have the following calibrators and controls when the screening result indicates that the pH is below the lower decision point in use:

(A) One calibrator at 4;

(B) One calibrator at 7;

(C) One control in the range of 2–2.8; and

(D) One control in the range 3.2– 4.

(v) If a pH screening test is used, an initial pH meter test must have the following calibrators and controls when the screening test result indicates that the pH is above the upper decision point in use:

(A) One calibrator at 7;

(B) One calibrator at 10;

(C) One control in the range of 10–10.8; and

(D) One control in the range of 11.2–12.

(3) Oxidizing adulterants. Initial tests for oxidizing adulterants must include a calibrator at the appropriate cutoff concentration for the compound of interest, a control without the compound of interest (i.e., a certified negative control), and a control with at least one of the compounds of interest at a measurable concentration. For nitrite, the licensee testing facility shall have one control in the range of 200–400 mcg/mL, one control in the range of 500–625 mcg/mL, and a control without nitrite (i.e., a certified negative control).

(4) Other adulterants. Initial tests for other adulterants must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

(e) Quality control requirements for initial drug tests.

(1) Any initial drug test performed by a licensee testing facility must use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. Licensee testing facilities may not use non-instrumented immunoassay testing devices that are pending HHS/SAMHSA review and approval for initial drug testing under this part. In addition, licensees and other entities may not take management actions on the basis of any drug test results obtained from non-instrumented devices that may be used for validity screening tests.

(2) Licensee testing facilities shall discard negative specimens or may pool them for use in the licensee testing facility's internal quality control program after certification by an HHS-certified laboratory that the specimens are negative and valid.

(3) Licensee testing facilities may perform multiple initial drug tests for the same drug or drug class, provided that all tests meet the cutoffs and quality control requirements of this part.

(4) Licensee testing facilities need not assess their false positive testing rates for drugs, because all specimens that test as positive on the initial tests for drugs and drug metabolites must be forwarded to an HHS-certified laboratory for initial and confirmatory testing.

(5) To ensure that the rate of false negative drug tests is kept to the minimum that the immunoassay technology supports, licensee testing facilities shall submit a minimum of 5 percent (or at least 1) of the specimens screened as negative from every analytical run to the HHS-certified laboratory.

(6) Quality control samples for each analytical run of specimens to be initially tested for drugs by the licensee testing facility must include —

(i) Sample(s) certified to contain no drug (i.e., negative urine samples);

(ii) At least one control fortified with a drug or drug metabolite targeted at 25 percent above the cutoff;

(iii) At least one control fortified with a drug or drug metabolite targeted at 75 percent of the cutoff.

(7) A minimum of 10 percent of all specimens in each analytical run must be quality control samples, as defined in paragraph (e)(6) of this section, that the licensee testing facility shall use for internal quality control purposes. One percent of each run or at least 1 sample (whichever is greater), must be blind performance test samples that appear as normal samples to the licensee testing facility technicians. Quality control samples are not forwarded to the HHS-certified laboratory for testing.

(8) Licensee testing facilities shall document the implementation of procedures to ensure that carryover does not contaminate the testing of a donor's specimen.

(f) Errors in testing. Each licensee testing facility shall investigate any testing errors or unsatisfactory performance discovered in the testing of quality control samples, in the testing of actual specimens, or through the processing of management reviews and/or MRO reviews, as well as any other errors or matters that could adversely reflect on the licensee testing facility's testing process. Whenever possible, the investigation must determine relevant facts and identify the root cause(s) of the testing or process error. The licensee testing facility shall take action to correct the cause(s) of any errors or unsatisfactory performance that are within the licensee testing facility's control. A record of the investigative findings and the corrective actions taken, where applicable, must be dated and signed by the individuals who are responsible for the day-to-day management of the licensee testing facility and reported to appropriate levels of management.

(g) Accuracy. Volumetric pipettes and measuring devices must be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors must be checked for accuracy and reproducibility before being placed in service, and periodically thereafter.

(h) Calibrators and controls. Calibrators and controls must be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions that are obtained from commercial manufacturers and are properly labeled as to content and concentration. Calibrators and controls may not be prepared from the same stock solution. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and when scheduled for expiration.

§26.139 Reporting initial validity and drug test results.

(a) The licensee testing facility shall report as negative all specimens that appear to be valid on the basis of validity screening or initial validity tests, or both, and are negative on the initial tests for drugs and drug metabolites. Except as provided in this part, non-negative test results from validity screening and initial validity and drug tests at the licensee testing facility may not be reported to licensee or other entity management.

(b) Except as provided in §§26.37 and 26.75(h), access to the results of initial tests must be limited to the licensee testing facility's staff, the MRO and MRO staff, the FFD program manager, and, when appropriate, EAP staff.

(c) The licensee testing facility shall provide qualified personnel, when required, to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on urinalysis results reported by the licensee testing facility.

(d) The licensee testing facility shall prepare the information required for the annual report to the NRC, as required in §26.217.

(e) The data in the annual report to the NRC must be presented for either the cutoff levels specified in this part, or for more stringent cutoff levels, if the FFD program uses more stringent cutoff levels for drugs and drug metabolites. If the FFD program tests for drugs and drug metabolites that are not specified in §26.31(d)(1), the summary must also include the number of positive test results and the cutoff levels used for those drugs and drug metabolites.

(f) The designated FFD program official shall use the available information from the licensee testing facility's validity and drug test results, the results of quality control testing performed at the licensee testing facility, and the results from testing the quality control samples that the licensee testing facility submits to the HHS-certified laboratory to evaluate continued

testing program effectiveness and detect any local trends in drugs of abuse that may require management action or FFD program adjustments. FFD program adjustments may include, but are not limited to, training enhancements, procedure changes, the expansion of the FFD program's drug panel to include additional drugs to be tested, or changes in the types of validity and drug testing devices, assays, or instruments used.

Subpart G – Laboratories Certified by the Department of Health and Human Services

§26.151 Purpose.

This subpart contains requirements for the HHS-certified laboratories that licensees and other entities who are subject to this part use for testing urine specimens for validity and the presence of drugs and drug metabolites.

§26.153 Using certified laboratories for testing urine specimens.

(a) Licensees and other entities who are subject to this part shall use only laboratories certified under the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs [published in the Federal Register on April 11, 1988 (53 FR 11970), and as amended, June 9, 1994 (59 FR 29908), November 13,1998 (63 FR 63483), and April 13, 2004 (69 FR 19643)] for specimen validity and drug testing, except as permitted under §26.31(d)(3)(ii). Information concerning the current certification status of laboratories is available from: the Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, Room 815, 5600 Fishers Lane, Rockwall 2 Bldg., Rockville, Maryland 20857.

(b) HHS-certified laboratories shall have the capability, at the same premises, to perform both initial and confirmatory tests for specimen validity and for each drug and drug metabolite for which the HHS-laboratory provides services to the licensee or other entity.

(c) An HHS-certified laboratory may not subcontract and shall perform all work with its own personnel and equipment unless otherwise authorized by the licensee or other entity.

(d) Licensees and other entities shall use only HHS-certified laboratories that agree to follow the same rigorous specimen testing, quality control, and chain-of-custody procedures when testing for more stringent cutoff levels as may be specified by licensees and other entities for the classes of drugs identified in this part, and for any other substances included in the licensees' or other entities' panels.

(e) Before awarding a contract to an HHS-certified laboratory, the licensee or other entity shall ensure that qualified personnel conduct a pre-award inspection and evaluation of the procedural aspects of the laboratory's drug testing operations. However, if an HHS-certified laboratory loses its certification, in whole or in part, a licensee or other entity may immediately begin using another HHS-certified laboratory that is being used by another licensee or entity who is subject to this part, in accordance with the requirements of §26.41(g)(5).

(f) All contracts between licensees or other entities who are subject to this part and HHS-certified laboratories must require the laboratory to implement all applicable requirements of this part. At a minimum, licensees' and other entities' contracts with HHS-certified laboratories must include the following requirements:

(1) Laboratory facilities shall comply with the applicable provisions of any State licensor requirements;

(2) The laboratory shall make available qualified personnel to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on urinalysis results reported by the HHS-certified laboratory;

(3) The laboratory shall maintain test records in confidence, consistent with the requirements of §26.39, and use them with the highest regard for individual privacy;

(4) Consistent with the principles established in Sec. 503 of Pub. L. 100-71, any employee of a licensee or other entity who is the subject of a drug test shall, upon written request, have access to the laboratory's records related to his or her validity and drug test and any records related to the results of any relevant certification, review, or revocation-of-certification proceedings;

(5) The laboratory may not enter into any relationship with the licensee's or other entity's MRO(s) that may be construed as a potential conflict of interest, and may not derive any financial benefit by having a licensee or other entity use a specific MRO; and

(6) The laboratory shall permit representatives of the NRC and any licensee or other entity using the laboratory's services to inspect the laboratory at any time, including unannounced inspections.

(g) If licensees or other entities use a form other than the current Federal custody-and-control form, licensees and other entities shall provide a memorandum to the laboratory explaining why a non-Federal form was used, but must ensure, at a minimum, that the form used contains all the required information on the Federal custody-and-control form.

§26.155 Laboratory personnel.

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

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

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

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

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

(iv) In addition to the requirements in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, the responsible person shall also have the following minimum qualifications:

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

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors that qualify the individual as an expert witness in forensic toxicology.

(2) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory, even if another individual has overall responsibility for an entire multi-specialty laboratory.

(3) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(4) This individual shall be responsible for ensuring that the laboratory has procedures that are complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedures must be reviewed, signed, and dated by this responsible person whenever the procedures are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory. This individual shall ensure that copies of all procedures and records of the dates on which they are in effect are maintained. (Specific contents of the procedures are described in §26.157.)

(5) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; maintaining acceptable analytical performance for all controls and standards; maintaining quality control testing; and assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(6) This individual shall be responsible for taking all remedial actions that may be necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, including errors in result reporting or in the analysis of performance testing results. This individual shall ensure that test

results are not reported until all corrective actions have been taken and he or she can assure that the test results provided are accurate and reliable.

(b) Certifying scientist.

(1) HHS-certified laboratories shall have one or more certifying scientists who review all pertinent data and quality control results to attest to the validity of the laboratory's test results.

(2) A certifying scientist shall be an individual with at least a bachelor’s degree in the chemical or biological sciences, medical technology, or an equivalent field who reviews all pertinent data and quality control results. The individual shall have training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain-of-custody procedures, quality control practices, and analytical procedures relevant to the results that the individual certifies. Relevant training and experience must also include the review, interpretation, and reporting of tests results; maintenance of chain of custody; and proper remedial action to be taken in response to aberrant test or quality control results, or a determination that test systems are out of control limits.

(3) A laboratory may designate certifying scientists who only certify results that are reported negative and certifying scientists who certify results that are reported both negative and non-negative.

(c) Day-to-day operations and supervision of analysts. HHS-certified laboratories shall assign one or more individuals who are responsible for day-to-day operations and supervision of the technical analysts. The designated individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or an equivalent field. The individual(s) shall also have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; review, interpretation, and reporting of test results;

maintenance of chain-of-custody; and proper remedial actions to be taken in response to aberrant test or quality control results, or the finding that test systems are out of control limits.

(d) Other personnel. Other technicians or nontechnical staff shall have the necessary training and skills for their assigned tasks.

(e) Training. HHS-certified laboratories shall make available continuing education programs to meet the needs of laboratory personnel.

(f) Files. At a minimum, each laboratory personnel file must include a resume, any professional certification(s) or license(s), a job description, and documentation to show that the individual has been properly trained to perform his or her job.

§26.157 Procedures.

(a) HHS-certified laboratories shall develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens.

(b) Written chain-of-custody procedures must describe the methods to be used to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage and shipping to another HHS-certified laboratory, if required, and continuing until final disposition of specimens.

(c) HHS-certified laboratories shall develop, implement, and maintain written standard operating procedures for each assay performed for licensees and other entities for drug and specimen validity testing. The procedures must include, but are not limited to, detailed descriptions of —

(1) The principles of each test;

(2) Preparation of reagents, standards, and controls;

(3) Calibration procedures;

(4) Derivation of results;

(5) Linearity of methods;

(6) Sensitivity of the methods;

(7) Cutoff values;

(8) Mechanisms for reporting results;

(9) Controls;

(10) Criteria for unacceptable specimens and results;

(11) Reagents and expiration dates; and

(12) References.

(d) HHS-certified laboratories shall develop, implement, and maintain written procedures for instrument setup and normal operation, including the following:

(1) A schedule for checking critical operating characteristics for all instruments;

(2) Tolerance limits for acceptable function checks; and

(3) Instructions for major troubleshooting and repair.

(e) HHS-certified laboratories shall develop, implement, and maintain written procedures for remedial actions to be taken when errors are detected or systems are out of acceptable limits. The laboratory shall maintain documentation that its personnel follow these procedures and take all necessary corrective actions. In addition, the laboratory shall have systems in place to verify all stages of testing and reporting and to document the verification.

§26.159 Assuring specimen security, chain of custody, and preservation.

(a) The HHS-certified laboratories performing services for licensees and other entities under this part shall be secure at all times. Each laboratory shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or areas where records are stored. Access to these secured areas must be limited to specially authorized individuals whose authorization is documented. All authorized visitors, and maintenance and service personnel, shall be escorted at all times in the laboratory, except personnel who are authorized to conduct inspections and audits on behalf of licensees, other entities, the NRC, or the Secretary of the Department of Health and Human Services, and emergency personnel (including but not limited to firefighters and medical rescue teams).

(b) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and shall compare information on specimen bottles within each package to the information on the accompanying custody-and-control forms. Any direct evidence of tampering or discrepancies in the information on the specimen bottles and the custody-and-control forms attached to the shipment must be reported to the licensee or other entity within 24 hours of the discovery and must be noted on the custody-and-control forms for each specimen contained in the package. Upon notification, the licensee or other entity shall ensure that an investigation is initiated to determine whether tampering has occurred. If the investigation determines that tampering has occurred, the licensee or other entity shall ensure that corrective actions are taken. If the licensee or other entity has reason to question the integrity and identity of the specimens, the specimens may not be tested and the licensee or other entity shall ensure that another collection occurs as soon as reasonably practical.

(c) The HHS-certified laboratory shall retain specimen bottles within the laboratory's accession area until all analyses have been completed. Laboratory personnel shall use aliquots and laboratory internal custody-and-control forms when conducting initial and confirmatory tests. The original specimen and the original custody-and-control form must remain in secure storage.

(d) The laboratory's internal custody-and-control form must allow for identification of the donor, and documentation of the testing process and transfers of custody of the specimen.

(e) Each time a specimen is handled or transferred within the laboratory, laboratory personnel shall document the date and purpose on the custody-and-control form and every individual in the chain shall be identified. Authorized technicians are responsible for each urine specimen or aliquot in their possession and shall sign and complete custody-and-control forms for those specimens or aliquots as they are received.

(f) If a specimen is to be transferred to a second HHS-certified laboratory, laboratory personnel shall ensure that the original custody-and-control form is packaged with its associated urine specimen bottle. Sealed and labeled specimen bottles, with their associated custody-and-control forms, being transferred from one laboratory to another must be placed in a second, tamper-evident shipping container 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 inaccessible without breaking a tamper-evident seal.

(g) Couriers, express carriers, and postal service personnel do not have direct access to the custody-and-control forms or the specimen bottles. Therefore, such personnel are not required to document chain of custody on the custody-and-control forms during transit.

Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided the courier, express carrier, or postal service.

(h) Specimens that do not receive an initial test within 7 days of arrival at the laboratory must be placed in secure refrigeration units for short-term storage. Temperatures may not exceed 6 ºC. The laboratory shall ensure proper storage conditions in the event of a prolonged power failure.

(i) Long-term frozen storage at a temperature of -20 ºC or less ensures that drug-positive, adulterated, substituted, and invalid urine specimens and Bottle B of a split specimen will be available for any necessary retests. Unless otherwise authorized in writing by the licensee or other entity, laboratories shall retain and place in properly secured long-term frozen storage all specimens reported as drug positive, adulterated, substituted, or invalid. At a minimum, such specimens must be stored for 1 year. Within this 1-year period, a licensee, other entity, or the NRC may ask the laboratory to retain the specimen for an additional period of time. If no retention request is received, the laboratory may discard the specimen after the end of 1 year. However, the laboratory shall retain any specimens under review or legal challenge until they are no longer needed.

(j) The laboratory shall discard a valid specimen that tests negative on initial or confirmatory drug tests or may pool such specimens for use in the laboratory's internal quality control program after certifying that the specimens are negative and valid.

§26.161 Cutoff levels for validity testing.

(a) Validity test results. Each validity test result must be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot.

(b) Initial validity testing.

(1) The HHS-certified laboratory shall test each specimen as follows:

(i) Determine the creatinine concentration;

(ii) Determine the specific gravity of every specimen for which the creatinine concentration is less than 20 mg/dL;

(iii) Determine the pH;

(iv) Perform one or more initial validity tests for oxidizing adulterants; and

(v) Perform additional validity tests, the choice of which depends upon the observed indicators or characteristics below, when the following conditions are observed:

(A) Abnormal physical characteristics;

(B) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of internal standards, unusual response); or

(C) Possible unidentified interfering substance or adulterant.

(2) If tests or observations indicate one or more of the following, there is reason to believe the donor may have diluted, substituted, or adulterated the specimen, and the laboratory shall subject the specimen to confirmatory validity testing:

(i) Creatinine is less than 20 mg/dL;

(ii) Using either a colorimetric pH test or pH meter, the pH of the specimen is found to meet any one of the following criteria:

(A) pH less than 3,

(B) pH equal to or greater than 11,

(C) pH equal to or greater than 3 and less than 4.5, or

(D) pH equal to or greater than 9 and less than 11;

(iii) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test;

(iv) The presence of chromium (VI) is indicated using either a general oxidant colorimetric test (with a cutoff equal to or greater than 50 mcg/mL chromium (VI) equivalents) or a chromium (VI) colorimetric test (chromium (VI) with a cutoff concentration equal to or greater than 50 mcg/mL);

(v) The presence of halogen (e.g., bleach, iodine, fluoride) is indicated using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite equivalents or equal to or greater than 50 mcg/mL chromium (VI) equivalents) or a halogen colorimetric test (halogen cutoff concentration equal to or greater than the LOD);

(vi) The presence of glutaraldehyde is indicated using either an aldehyde test (aldehyde present) or the characteristic immunoassay response is observed on one or more drug immunoassay tests;

(vii) The presence of pyridine (pyridinium chlorochromate) is indicated using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite equivalents or equal to or greater than 50 mcg/mL chromium (VI) equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL);

(viii) The presence of a surfactant is indicated by using a surfactant colorimetric test with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate equivalent; or

(ix) The specimen provides evidence of adulterants, including, but not limited to the following:

(A) Abnormal physical characteristics,

(B) Reactions or responses characteristic of an adulterant obtained during the initial test, or

(C) Possible unidentified interfering substance or adulterant, demonstrated by interference occurring on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained).

(c) Results indicating an adulterated specimen. The laboratory shall report a specimen as adulterated when the specimen yields any one or more of the following validity testing results:

(1) The pH is less than 3, or equal to or greater than 11, using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(2) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 50 mcg/mL chromium (VI) equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOD of the confirmatory test on the second aliquot;

(4) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI) equivalents) or a halogen colorimetric test (halogen concentration equal to or greater than the LOD) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOD of the confirmatory test on the second aliquot;

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the specimen yields the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and GC/MS for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOD of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI) equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and GC/MS for the confirmatory test with the pyridine concentration equal to or greater than the LOD of the analysis on the second aliquot;

(7) The presence of a surfactant is verified by using a surfactant colorimetric test with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate equivalent for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate equivalent on the second aliquot; or

(8) The presence of any other adulterant not specified in paragraphs (c)(3) through (c)(7) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(d) Results indicating a substituted specimen. The laboratory shall report a specimen as substituted when the specimen's creatinine concentration is less than 2 mg/dL and its specific gravity is less than or equal to 1.0010, or equal to or greater than 1.0200, on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.

(e) Results indicating a dilute specimen. The laboratory shall report a specimen as dilute when the specimen's creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and its specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(f) Results indicating an invalid specimen. The laboratory shall report a specimen as invalid when the laboratory obtains any one or more of the following validity testing results:

(1) Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(2) The pH is equal to or greater than 3 and less than 4.5, or equal to or greater than 9 and less than 11, using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(3) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test, or equal to or greater than 200 mcg/mL nitrite equivalents using a general oxidant colorimetric test for both the initial test and the confirmatory test, or, using either initial test, the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL using a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(4) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial test and the confirmatory test on two separate aliquots;

(5) The possible presence of a halogen (e.g., bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOD for both the initial test and the confirmatory test on two separate aliquots or relying on the odor of the specimen as the initial test;

(6) The possible presence of glutaraldehyde is determined using the same aldehyde test (aldehyde present) or the characteristic immunoassay response is observed on one or more drug immunoassay tests for both the initial test and the confirmatory test on two separate aliquots;

(7) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with cutoffs equal to or greater than 200 mcg/mL nitrite equivalents, equal to or greater than 50 mcg/mL chromium (VI) equivalents, or a halogen concentration equal to or greater than the LOD) for both the initial test and the confirmatory test on two separate aliquots;

(8) The possible presence of a surfactant is determined using the same surfactant colorimetric test with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate

equivalent for both the initial test and the confirmatory test on two separate aliquots or a foam/shake test for the initial test;

(9) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained);

(10) Interference with the drug confirmation assay occurs on at least two separate aliquots of the specimen, and the laboratory is unable to identify the interfering substance;

(11) The physical appearance of the specimen indicates that testing may damage the laboratory's equipment; or

(12) The physical appearances of Bottles A and B (when a split specimen collection is used) are clearly different, and either the test result for Bottle A indicated it is an invalid specimen or the specimen in Bottle A was screened negative for drugs, or both.

(g) Additional testing by a second laboratory. If the presence of an interfering substance/adulterant is suspected that could make a test result invalid, but it cannot be identified (e.g., a new adulterant), laboratory personnel shall consult with the licensee's or other entity's MRO and, with the MRO's agreement, shall send the specimen to another HHS-certified laboratory that has the capability to identify the suspected substance.

(h) More stringent validity test cutoff levels are prohibited. Licensees and other entities may not specify more stringent cutoff levels for validity tests than those specified in this section.

§26.163 Cutoff levels for drugs and drug metabolites.

(a) Initial drug testing.

(1) HHS-certified laboratories shall apply the following cutoff levels for initial testing of specimens to determine whether they are negative for the indicated drugs and drug

metabolites, except if validity testing indicates that the specimen is dilute or the licensee or other entity has established more stringent cutoff levels:

Initial test cutoff levels for drugs and drug metabolites

Drug or Metabolites	Cutoff level (ng/mL)
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	2,000
Phencyclidine	25
Amphetamines	1,000

(2) If confirmatory validity testing indicates that a specimen is dilute, the HHS-certified laboratory shall use analytical kits approved by the Food and Drug Administration that have the lowest concentration levels marketed for the technology(ies) being used to conduct initial testing of the specimen for drugs or drug metabolites. The laboratory shall compare the responses of the dilute specimen to the cutoff calibrator in each of the drug classes. If the response is within 50 percent of the cutoff, the HHS-certified laboratory shall inform the licensee's or other entity's MRO. At the licensee's or other entity's discretion, as documented in the FFD program policies and procedures, the MRO may direct the laboratory to test the specimen for drugs and/or drug metabolites down to the confirmatory assay's limit of detection (LOD). The laboratory shall report the results of the special analysis, if requested, to the MRO.

(b) Confirmatory drug testing.

(1) A specimen that is identified as positive on an initial drug test must be subject to confirmatory testing for the class(es) of drugs for which the specimen initially tested positive. The HHS-certified laboratory shall apply the confirmatory cutoff levels specified in this paragraph, except if confirmatory validity testing indicates that the specimen is dilute or the licensee or other entity has established more stringent cutoff levels.

Confirmatory test cutoff levels for drugs and drug metabolites

Drug or Metabolites	Cutoff level (ng/mL)
Marijuana metabolite[1]	15
Cocaine metabolite[2]	150
Opiates:	
Morphine	2000
Codeine	2000
6-acetylmorphine[3]	10
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine[4]	500

[1] As delta-9-tetrahydrocannabinol-9-carboxylic acid.

[2] As benzoylecgonine.

[3] Test for 6-AM when the confirmatory test shows a morphine concentration exceeding 2,000 ng/mL.

[4] Specimen must also contain amphetamine at a concentration equal to or greater than 200 ng/mL.

(2) Each confirmatory drug test must provide a quantitative result. When the concentration of a drug or metabolite exceeds the linear range of the standard curve, the laboratory may record the result as "exceeds the linear range of the test" or as “equal to or greater than <insert the value for the upper limit of the linear range>,” or may dilute an aliquot of the specimen to obtain an accurate quantitative result when the concentration is above the upper limit of the linear range.

§26.165 Testing split specimens and retesting single specimens.

(a) Split specimens.

(1) If a specimen has been split into Bottle A and Bottle B at the collection site, and the specimen was not initially tested at a licensee testing facility, then the HHS-certified laboratory shall perform initial and confirmatory validity and drug testing, if required, of the specimen in Bottle A.

(2) If a specimen was initially tested at a licensee testing facility and non-negative results were obtained, then the HHS-certified laboratory shall perform initial and confirmatory testing, if required, of the specimen in Bottle A.

(3) At the licensee's or other entity's discretion, Bottle B must either be forwarded to the laboratory or maintained in secure storage by the licensee or other entity. If the specimen in Bottle A is free of any evidence of drugs or drug metabolites, and is a valid specimen, then the licensee, other entity, or laboratory may discard the specimen in Bottle B.

(4) If initial and confirmatory test results from the specimen in Bottle A are positive for one or more drugs or drug metabolites, or if validity testing at the HHS-certified laboratory shows that the specimen has been subject to adulteration, substitution, or other means of subversion, the laboratory shall report the results to the MRO. Within 3 business days (Monday through Friday, excluding holidays) of being notified by the MRO that the donor's specimen yielded a non-negative test result, the donor may request that the split specimen in Bottle B be tested by another HHS-certified laboratory. The MRO shall inform the donor of this option, and the specimen in Bottle B may be tested only at the donor's request. The donor shall provide his or her written permission for the testing of Bottle B and neither the licensee, MRO, NRC, nor any other entity may order testing of Bottle B without the donor's written permission.

(5) If the donor requests that the specimen in Bottle B be tested, the HHS-certified laboratory shall forward Bottle B to a second HHS-certified laboratory that did not test the

specimen in Bottle A as soon as reasonably practical and not more than one business day following the day of the donor's request.

(6) The HHS-certified laboratory that tests the specimen in Bottle B shall provide quantitative test results to the MRO and the MRO shall provide them to the donor.

(b) Donor request to MRO for a retest of a single specimen.

(1) For a drug-positive, adulterated, or substituted result reported on a single specimen of 30 mL or more which the donor submitted to the licensee or other entity, a donor may request (through the MRO) that an aliquot from the single specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory. The MRO shall inform the donor of the option for a retest and the donor shall request the retest within 3 business days after notification by the MRO of the non-negative test result. The donor shall provide his or her written permission for the retest and neither the licensee, MRO, NRC, nor any other entity may order retesting of the specimen without the donor's written permission, except as provided in §26.185(m).

(2) For a single specimen that the laboratory has reported as invalid, a donor may not request that an aliquot from the single specimen be tested by a second HHS-certified laboratory. If the donor requests testing of the specimen, the HHS-certified laboratory shall forward the specimen to a second HHS-certified laboratory that did not test the specimen as soon as reasonably practical and not more than one business day following the day of the donor's request.

(c) Retesting a specimen for drugs.

(1) The second laboratory shall use its standard confirmatory drug test when retesting an aliquot of a single specimen or testing Bottle B of a split specimen for the drug(s) or drug metabolite(s) for which the first laboratory reported a positive result(s).

(2) Because some drugs or drug metabolites may deteriorate during storage, the retest by the second laboratory is not subject to a specific drug cutoff level, but must provide data sufficient to confirm the presence of the drug(s) or drug metabolite(s) down to the assay's LOD.

(3) If the second laboratory fails to reconfirm the presence of the drug(s) or drug metabolite(s) for which the first laboratory reported a positive result(s), the second laboratory shall attempt to determine the reason for not reconfirming the first laboratory's findings by conducting specimen validity tests. The second laboratory shall conduct the same specimen validity tests it would conduct on a single specimen or the specimen in Bottle A of a split specimen.

(4) The second laboratory shall report all results to the licensee's or other entity's MRO.

(d) Retesting a specimen for adulterants. A second laboratory shall use the appropriate confirmatory validity test and criteria specified in §26.161(c) to reconfirm an adulterant result when retesting an aliquot from a single specimen or when testing Bottle B of a split specimen. The second laboratory may only conduct the confirmatory validity test needed to reconfirm the adulterant result reported by the first laboratory.

(e) Retesting a specimen for substitution. A second laboratory shall use its confirmatory creatinine and confirmatory specific gravity tests, when retesting an aliquot of a single specimen or testing Bottle B of a split specimen, to reconfirm that the creatinine concentration was less than 2 mg/dL and the specific gravity was less than or equal to 1.0010 or equal to or greater than 1.0200. However, the second laboratory shall apply the cutoff levels for a substituted result in this part and shall report the results as non-confirmed if the second laboratory's results exceed the original test cutoff parameters. The second laboratory may only conduct the confirmatory creatinine and specific gravity tests to reconfirm the substitution result reported by the first laboratory.

(f) Management actions and sanctions.

(1) If the MRO confirms a non-negative test result(s) from the first HHS-certified laboratory and the donor requests testing of Bottle B of a split specimen or retesting of an aliquot from a single specimen, the licensee or other entity shall administratively withdraw the individual's authorization on the basis of the first confirmed non-negative test result until the results of testing Bottle B or retesting an aliquot of the single specimen are available and have been reviewed by the MRO. If the MRO reports that the results of testing Bottle B or retesting the aliquot of a single specimen confirm any of the original non-negative test result(s), the licensee or other entity shall impose the appropriate sanctions specified in Subpart D of this part. If the results of testing Bottle B or retesting the aliquot of a single specimen are negative, the licensee or other entity —

(i) May not impose any sanctions on the individual;

(ii) Shall eliminate from the tested individual's personnel and other records any matter that could link the individual to the temporary administrative action;

(iii) May not disclose the temporary administrative action in response to a suitable inquiry conducted under the provisions of §26.63 or to any other inquiry or investigation required in this chapter. To ensure that no records have been retained, access to the system of files and records must be provided to personnel conducting reviews, inquiries into allegations, or audits under the provisions of §26.41, or to NRC inspectors; and

(iv) Shall provide the tested individual with a written statement that the records specified in §§26.213 and §26.215 have not been retained and shall inform the individual in writing that the temporary administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for self-disclosure of potentially disqualifying FFD information.

(2) If a donor requests that Bottle B be tested or that an aliquot of a single specimen be retested, and either Bottle B or the single specimen are not available due to circumstances

outside of the donor's control (including, but not limited to, circumstances in which there is an insufficient quantity of the single specimen to permit retesting, either Bottle B or the original single specimen is lost in transit to the second HHS-certified laboratory, Bottle B has been lost), the MRO shall cancel the test. The licensee or other entity shall eliminate from the donor's personnel and other records any matter that could link the donor to the original non-negative test result(s) and any temporary administrative action, and may not impose any sanctions on the donor for a cancelled test. If the original specimen was collected for random, for-cause, or post-event testing, the licensee or other entity shall document only that the test was performed and cancelled. If the original specimen was collected for pre-access or followup testing, the MRO shall direct the licensee or other entity to collect another specimen for testing as soon as reasonably practical. If test results from the second specimen collected are non-negative and the MRO determines that the donor has violated the FFD policy, the licensee or other entity shall impose the appropriate sanctions specified in Subpart D of this part, but may not consider the original confirmed non-negative test result in determining the appropriate sanctions.

§26.167 Quality assurance and quality control.

(a) Quality assurance program. Each HHS-certified laboratory shall have a quality assurance program that encompasses all aspects of the testing process, including, but not limited to, specimen accessioning, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrators and controls, and validation of analytical procedures. The performance characteristics (e.g., accuracy, precision, LOD, limit of quantitation (LOQ), specificity) of each test must be validated and documented for each test. Validation of procedures must document that carryover does not affect the donor's specimen results. Periodic re-verification of analytical procedures is required. Quality assurance procedures must be designed, implemented, and reviewed to monitor the conduct of each step of the testing process.

(b) Calibrators and controls required. Each analytical run of specimens for which an initial or confirmatory validity test, or an initial or confirmatory drug test, is being performed must include the appropriate calibrators and controls.

(c) Quality control requirements for performing initial and confirmatory validity tests.

(1) Requirements for performing creatinine tests.

(i) The creatinine concentration must be measured to 1 decimal place on both the initial and the confirmatory creatinine tests.

(ii) The initial creatinine test must have a calibrator at 2 mg/dL.

(iii) The initial creatinine test must have a control in the range of 1–1.5 mg/dL, a control in the range of 3–20 mg/dL, and a control in the range of 21–25 mg/dL.

(iv) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have a calibrator at 2 mg/dL, a control in the range of 1–1.5 mg/dL, and a control in the range of 3–4 mg/dL.

(2) Requirements for performing specific gravity tests.

(i) The refractometer must report and display the specific gravity to 4 decimal places, and must be interfaced with a laboratory information management system (LIMS), or computer, and/or generate a hard copy or digital electronic display to document the numerical result.

(ii) The initial and confirmatory specific gravity tests must have a calibrator or control at 1.0000.

(iii) The initial and confirmatory specific gravity tests must have the following controls:

(A) One control targeted at 1.0020;

(B) One control in the range of 1.0040–1.0180; and

(C) One control equal to or greater than 1.0200 but not greater than 1.0250.

(3) Requirements for performing pH tests.

(i) Colorimetric pH tests that have the dynamic range of 2–12 to support the 3 and 11 pH cutoffs and pH meters must be capable of measuring pH to 1 decimal place. Dipsticks, colorimetric pH tests, and pH paper that have a narrow dynamic range and do not support the 2–12 pH cutoffs may be used only to determine whether initial validity tests must be performed. At a minimum, pH screening tests must have the following controls:

(A) One control below the lower decision point in use;

(B) One control between the decision points in use; and

(C) One control above the upper decision point in use.

(ii) An initial colorimetric pH test must have the following calibrators and controls:

(A) One calibrator at 3;

(B) One calibrator at 11;

(C) One control in the range of 2–2.8;

(D) One control in the range 3.2–4;

(E) One control in the range of 4.5–9;

(F) One control in the range of 10–10.8;

(G) One control in the range of 11.2–12.

(iii) If a pH screening test is not used, an initial pH meter test must have the following calibrators and controls:

(A) One calibrator at 4;

(B) One calibrator at 7;

(C) One calibrator at 10;

(D) One control in the range of 2–2.8;

(E) One control in the range 3.2–4;

(F) One control in the range of 10–10.8; and

(G) One control in the range of 11.2–12.

(iv) If a pH screening test is used, an initial or confirmatory pH meter test must have the following calibrators and controls when the screening result indicates that the pH is below the lower decision point in use:

(A) One calibrator at 4;

(B) One calibrator at 7;

(C) One control in the range of 2–2.8; and

(D) One control in the range 3.2–4.

(v) If a pH screening test is used, an initial or confirmatory pH meter test must have the following calibrators and controls when the screening result indicates that the pH is above the upper decision point in use:

(A) One calibrator at 7;

(B) One calibrator at 10;

(C) One control in the range of 10–10.8; and

(D) One control in the range of 11.2–12.

(4) Requirements for performing oxidizing adulterant tests.

(i) Initial tests for oxidizing adulterants must include a calibrator at the appropriate cutoff concentration for the compound of interest, a control without the compound of interest (i.e., a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration.

(ii) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each analytical run must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

(5) Requirements for performing nitrite tests. The initial and confirmatory nitrite tests must have a calibrator at the cutoff concentration, a control without nitrite (i.e., certified negative urine), one control in the range of 200–400 mcg/mL, and one control in the range of 500–625 mcg/mL.

(6) Requirements for performing "other" adulterant tests.

(i) The initial and confirmatory tests for any "other" adulterant that may be identified in the future must satisfy the requirements in §26.161(a).

(ii) The confirmatory test for “other” adulterants must use a different analytical principle or chemical reaction than that used for the initial test.

(iii) The initial and confirmatory tests for “other” adulterants must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

(d) Quality control requirements for performing initial drug tests.

(1) Any initial drug test performed by an HHS-certified laboratory must use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. Non-instrumented immunoassay testing devices that are pending HHS/Substance Abuse and Mental Health Services Administration (SAMHSA) review and approval may not be used for initial drug testing under this part.

(2) HHS-certified laboratories may perform multiple initial drug tests for the same drug or drug class, provided that all tests meet the cutoffs and quality control requirements of this part.

(3) Each analytical run of specimens for initial testing must include —

(i) Sample(s) certified to contain no drug (i.e., negative urine samples);

(ii) At least one control fortified with a drug or drug metabolite targeted at 25 percent above the cutoff;

(iii) At least one control fortified with a drug or drug metabolite targeted at 75 percent of the cutoff;

(iv) A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff (after acceptable values are obtained for the known calibrators, those values will be used to calculate sample data);

(v) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples; and

(vi) One percent of each run, with a minimum of at least one sample, must be the laboratory's blind quality control samples to appear as routine specimens to the laboratory analysts.

(e) Quality control requirements for performing confirmatory drug tests.

(1) Confirmatory tests for drugs and drug metabolites must be performed using gas chromatography/mass spectrometry (GC/MS) or other confirmatory test methodologies that HHS-certified laboratories are permitted to use in Federal workplace drug testing programs for this purpose.

(2) At least 10 percent of the samples in each analytical run of specimens must be calibrators and controls. Each analytical run of specimens that are subjected to confirmatory testing must include —

(i) Sample(s) certified to contain no drug (i.e., negative urine samples);

(ii) Positive calibrator(s) and control(s) fortified with a drug or drug metabolite;

(iii) At least one control fortified with a drug or drug metabolite targeted at 25 percent above the cutoff; and

(iv) At least one calibrator or control that is targeted at or below 40 percent of the cutoff.

(f) Blind performance testing. Each licensee and other entity shall submit blind performance test samples to the HHS-certified laboratory.

(1) During the initial 90-day period of any contract with an HHS-certified laboratory (not including rewritten or renewed contracts), each licensee or other entity shall submit blind performance test samples to each HHS-certified laboratory with whom it contracts in the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 100 blind performance specimens) or 30 blind performance test samples, whichever is greater.

(2) Following the initial 90-day period, the number of blind performance test samples submitted per quarter must be a minimum of 1 percent of all specimens (up to a maximum of 100) or 10 blind performance test samples, whichever is greater. Both during the initial 90-day period and quarterly thereafter, licensees and other entities should attempt to submit blind performance test samples at a frequency that corresponds to the submission frequency for other specimens.

(3) Approximately 15 percent of the blind performance test samples submitted to the laboratory must be positive for one or more drugs per sample so that all of the drugs for which the FFD program is testing are included each quarter. The positive samples must be spiked only with those drugs for which the FFD program is testing and spiked with concentrations between 60–80 percent of the initial cutoff values for the panel of drugs established herein, or of any lower cutoff values established by the licensee or other entity. To challenge the HHS-certified laboratory's ability to determine specimen validity, the licensee or other entity shall submit blind samples each quarter that are appropriately adulterated, diluted, or substituted, in

the amount of 5 percent of the specimens submitted that quarter or at least 3 samples per quarter (one each that is adulterated, diluted, or substituted), whichever is greater.

(4) Approximately 80 percent of the blind performance test samples submitted to the laboratory each quarter must be blank (i.e., certified to contain no drug).

(5) Licensees and other entities shall use only blind performance test samples that have been certified by the supplier to be negative (i.e., as certified by immunoassay and confirmatory testing), drug positive [i.e., certified by immunoassay and confirmatory testing to contain one or more drug(s) or drug metabolite(s)], adulterated (i.e., certified to be adulterated with a specific adulterant using an appropriate confirmatory validity test), or substituted (i.e., the creatinine concentration and specific gravity satisfy the criteria for a substituted specimen using confirmatory creatinine and specific gravity tests, respectively). The supplier shall also provide the expiration date for each blind performance test sample to ensure that each quality control sample will give the expected result when it is submitted and correctly tested by a laboratory before the expiration date. In addition, —

(i) Drug performance testing samples must satisfy, but are not limited to, one of the following criteria:

(A) The drug or drug metabolite concentration in the sample must be at least 20 percent above the designated cutoff for either the initial drug test or the confirmatory drug test, depending upon which is to be evaluated;

(B) For retest samples, the drug or drug metabolite concentration may be as low as 40 percent of the cutoff;

(C) For routine samples, the drug or drug metabolite concentration may be below the cutoff for special purposes;

(D) A negative sample may not contain the target drug analyte at a concentration greater than 10 percent of the confirmatory cutoff; and

(E) Samples may be fortified with interfering substances.

(ii) Validity performance testing samples must satisfy, but are not limited to, one of the following criteria:

(A) The nitrite concentration must be at least 20 percent above the cutoff;

(B) The pH must be less than 2.75 or greater than 11.25;

(C) The concentration of an oxidant will be at a level sufficient to challenge a laboratory's ability to identify and confirm the oxidant;

(D) The creatinine concentration must be between 0 and 20 mg/dL; and

(E) The specific gravity must be less than or equal to 1.0050 or between 1.0170 and 1.0230.

(g) Errors in testing. The licensee or other entity shall ensure that the HHS-certified laboratory investigates any testing errors or unsatisfactory performance discovered in blind performance testing, in the testing of actual specimens, or through the processing of reviews, as well as any other errors or matters that could adversely reflect on the testing process.

(1) Whenever possible, the investigation must determine relevant facts and identify the root cause(s) of the testing or process error. The licensee or other entity, and the HHS-certified laboratory, shall take action to correct the causes of any errors or unsatisfactory performance that are within their control. Sufficient records shall be maintained to furnish evidence of activities affecting quality. The licensee or other entity shall assure that the cause of the condition is determined and the corrective action taken to preclude repetition. The identification of the significant condition, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

(2) Should a false positive error occur on a blind performance test sample or on a regular specimen, the licensee or other entity 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 that the error could have been systematic, the licensee or other entity may also require review and re-analysis of previously run specimens.

(3) Should a false positive error occur on a blind performance test sample and the error is determined to be technical or methodological, the licensee or other entity shall instruct the laboratory to provide all quality control data from the batch or analytical run of specimens that included a false positive sample. In addition, the licensee or other entity shall require the laboratory to retest all specimens that analyzed as positive for that drug or metabolite, or as non-negative in validity testing, 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 laboratory's certifying scientist. The licensee or other entity and the NRC also may require an onsite review of the laboratory, which may be conducted unannounced during any hours of operation of the laboratory.

(h) Accuracy. Volumetric pipettes and measuring devices must be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedures. Automatic pipetttes and dilutors must be checked for accuracy and reproducibility both before being placed in service and periodically thereafter.

(i) Calibrators and controls. Laboratory calibrators and controls must be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions that are obtained from commercial manufacturers and are properly labeled as to content and concentration. Calibrators and controls may not be prepared from the same stock solution. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and when scheduled for expiration.

§26.169 Reporting results.

(a) The HHS-certified laboratory shall report test results to the licensee's or other entity's MRO within 5 business days after receiving the specimen from the licensee or other entity. Before reporting any test result to the MRO, the laboratory's certifying scientist shall certify the result as correct. The report must identify the substances for which testing was performed; the results of the validity and drug tests; the cutoff levels for each; any indications of tampering, adulteration, or substitution that may be present; the specimen identification number assigned by the licensee or other entity; and the specimen identification number assigned by the laboratory.

(b) The HHS-certified laboratory shall report as negative all specimens that are negative on the initial or confirmatory drug and validity tests. Specimens that test as non-negative on the confirmatory analysis must be reported to the MRO as positive for a specific drug(s) or drug metabolite(s), or as meeting the criteria for an adulterated, substituted, or dilute specimen.

(c) If licensees or other entities specify cutoff levels for drugs or drug metabolites that are more stringent than those specified in this part, the laboratory need only conduct the more stringent tests and shall report the results of the initial and confirmatory tests only for the more stringent cutoff levels.

(d) For a specimen that is found to be dilute, adulterated, or substituted, the laboratory shall report the specimen as dilute, adulterated, or substituted and, when applicable, shall provide the MRO with the numerical values that support the reported result. The MRO may not disclose the numerical values to the licensee or other entity, except as permitted in §26.37(b). If the numerical values for creatinine are below the LOD, the laboratory shall report to the MRO "creatinine none detected" (i.e., substituted) along with the numerical values. For a specimen that has an invalid result, the laboratory shall contact the MRO and both will decide whether testing by another certified laboratory would be useful in being able to report a positive or

adulterated result. Such contact may occur through any secure electronic means (e.g., telephone, fax, email). If no further testing is necessary, the laboratory shall report the invalid result to the MRO.

(e) The laboratory shall report all non-negative test results for a specimen to the MRO. For example, a specimen may be both adulterated and positive for one or more specific drugs.

(f) The laboratory shall provide numerical values for non-negative confirmatory test results when the MRO requests such information. The MRO's request may be either a general request covering all such results or a specific case-by-case request. When the concentration of a drug, metabolite, or adulterant exceeds the linear range of the standard curve, the laboratory may report to the MRO that the quantitative value "exceeds the linear range of the test," that the quantitative value is "equal to or greater than <insert the value for the upper limit of the linear range>," or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen. The MRO may not disclose quantitative test results to the licensee or other entity, but shall report only whether the specimen was drug-positive (and for which analyte), adulterated, substituted, invalid, or negative, except as permitted under §26.37(b). This paragraph does not preclude either the laboratory or the MRO from providing program performance data, as required under §26.217.

(g) The laboratory shall routinely provide quantitative values for confirmatory opiate test results for morphine or codeine that are greater than or equal to 15,000 ng/mL, even if the MRO has not requested quantitative values for the test result.

(h) The laboratory may transmit results to the MRO by various electronic means (e.g., teleprinters, facsimile, or computer) in a manner designed to ensure the confidentiality of the information. The laboratory may not provide results verbally by telephone. The licensee or other entity, directly or through the HHS-certified laboratory, shall ensure the security of the

data transmission and ensure only authorized access to any data transmission, storage, and retrieval system.

(i) For negative test results, the HHS-certified laboratory may fax, courier, mail, or electronically transmit a computer-generated electronic report and/or a legible image or copy of the completed custody-and-control form to the MRO. However, for non-negative results, the laboratory shall fax, courier, mail, or electronically transmit a legible image or copy of the completed custody-and-control form to the MRO.

(j) For a specimen that has a non-negative result, the laboratory shall retain the original custody-and-control form and transmit to the MRO a copy of the original custody-and-control form signed by a certifying scientist.

(k) The HHS-certified laboratory shall provide to the licensee's or other entity's official responsible for coordination of the FFD program an annual statistical summary of urinalysis testing, which may not include any personal identifying information. In order to avoid sending data from which it is likely that information about a donor's test result can be readily inferred, the laboratory may not send a summary report if the licensee or other entity has fewer than 10 specimen test results in a 1-year period. The summary report must include test results that were reported within the year period. The laboratory shall send the summary report to the licensee or other entity within 14 calendar days after the end of the 1-year period covered by the report. The statistics must be presented either for the cutoff levels specified in this part or for any more stringent cutoff levels that the licensee or other entity may specify. The HHS-certified laboratory shall make available quantitative results for all specimens tested when requested by the NRC, licensee, or other entity for whom the laboratory is performing drug-testing services. If the FFD program tests for additional drugs beyond those listed in §26.31(d), the summary must include drug test results for the additional drugs. The summary report must contain the following information:

(1) Total number of specimens received;

(2) Number of specimens reported as —

(i) Negative, and

(ii) Negative and dilute;

(3) Number of specimens reported as positive on confirmatory tests by drug or drug metabolite for which testing is conducted, including, but not limited to —

(i) Marijuana metabolite;

(ii) Cocaine metabolite;

(iii) Opiates (total);

(A) Codeine,

(B) Morphine, and

(C) 6-AM;

(iv) Phencyclidine;

(v) Amphetamines (total);

(A) Amphetamine, and

(B) Methamphetamine;

(4) Total number of specimens reported as adulterated;

(5) Total number of specimens reported as substituted;

(6) Total number of specimens reported as drug positive and dilute; and

(7) Total number of specimens reported as invalid.

Subpart H – Determining Fitness-for-Duty Policy Violations and Determining Fitness

§26.181 Purpose.

This subpart contains requirements for determining whether a donor has violated the FFD policy and for making a determination of fitness.

§26.183 Medical review officer.

(a) Qualifications. The MRO shall be knowledgeable of this part and of the FFD policies of the licensees and other entities for whom the MRO provides services. The MRO shall be a physician holding either a Doctor of Medicine or Doctor of Osteopathy degree who is licensed to practice medicine by any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. By **[insert date 2 years after publication of the final rule in the Federal Register]**, the MRO shall have passed an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of Federally mandated drug tests.

(b) Relationships. The MRO may be an employee of the licensee or other entity or a contractor. However, the MRO may not be an employee or agent of, or have any financial interest in, an HHS-certified laboratory or a contracted operator of a licensee testing facility for whom the MRO reviews drug test results. Additionally, the MRO may not derive any financial benefit by having the licensee or other entity use a specific drug testing laboratory or licensee testing facility operating contractor and may not have any agreement with such parties that may be construed as a potential conflict of interest.

(c) Responsibilities. The primary role of the MRO is to review and interpret non-negative test results obtained through the licensee's or other entity's testing program and to identify any evidence of subversion of the testing process. The MRO is also responsible for identifying any

issues associated with collecting and testing specimens, and for advising and assisting FFD program management in planning and overseeing the overall FFD program.

(1) In carrying out these responsibilities, the MRO shall examine alternate medical explanations for any non-negative test result. This action may include, but is not limited to, conducting a medical interview with the donor, reviewing the donor's medical history, or reviewing any other relevant biomedical factors. The MRO shall review all medical records that the donor may make available when a non-negative test result could have resulted from responsible use of legally prescribed medication, a documented condition or disease state, or the demonstrated physiology of the donor.

(2) The MRO may only consider the results of tests of specimens that are collected and processed in accordance with this part, including the results of testing 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 part.

(d) MRO staff. Individuals who provide administrative support to the MRO may be employees of a licensee or other entity, employees of the MRO, or employees of an organization with whom a licensee or other entity contracts for MRO services.

(1) Direction of MRO staff activities. MROs shall be directly responsible for all administrative, technical, and professional activities of individuals who are serving MRO staff functions under his or her direction.

(i) The duties of MRO staff must be maintained independent from any other activity or interest of a licensee or other entity, in order to protect the integrity of the MRO function and donors' privacy.

(ii) An MRO's responsibilities for directing MRO staff must include, but are not limited to, ensuring that —

(A) The procedures being performed by MRO staff meet NRC regulations and HHS' and professional standards of practice;

(B) Records and other donor personal information are maintained confidential by MRO staff and are not released to other individuals or entities, except as permitted under this part;

(C) Data transmission is secure; and

(D) Drug test results are reported to the licensee's or other entity's designated reviewing official only in accordance with the requirements of this part.

(iii) The MRO may not delegate any of his or her responsibilities for directing MRO staff to any other individual or entity, except another MRO.

(2) MRO staff responsibilities. MRO staff may perform routine administrative support functions, including receiving test results, reviewing negative test results, and scheduling interviews for the MRO.

(i) The staff under the direction of the MRO may receive, review, and report negative test results to the licensee's or other entity's designated representative.

(ii) The staff reviews of non-negative drug test results must be limited to reviewing the custody-and-control form to determine whether it contains any errors that may require corrective action and to ensure that it is consistent with the information on the MRO's copy. The staff may resolve errors in custody-and-control forms that require corrective action(s), but shall forward the custody-and-control forms to the MRO for review and approval of the resolution.

(iii) The staff may not conduct interviews with donors to discuss non-negative drug test results nor request medical information from a donor. Only the MRO may request and review medical information related to a non-negative drug test result or other matter from a donor.

(iv) Staff may not report nor discuss any non-negative test results received from the HHS-certified laboratory with any individuals other than the MRO and other MRO staff.

§26.185 Determining a fitness-for-duty policy violation.

(a) MRO review required. A non-negative drug test result does not automatically identify an individual as having used drugs in violation of the NRC's regulations, or the licensee's or other entity's FFD policy, or as having attempted to subvert the testing process. An individual who has a detailed knowledge of possible alternate medical explanations is essential to the review of the results. The MRO shall review all non-negative test results from the HHS-certified laboratory to determine whether the donor has violated the FFD policy before reporting the results to the licensee's or other entity's designated representative.

(b) Reporting of initial test results prohibited. Neither the MRO nor MRO staff may report non-negative initial test results to the licensee or other entity that are received from the HHS-certified laboratory.

(c) Discussion with the donor. Before determining that a non-negative test result or other occurrence is an FFD policy violation and reporting it to the licensee or other entity, the MRO shall give the donor an opportunity to discuss the test result or other occurrence with the MRO, except as described in paragraph (d) of this section. After this discussion, if the MRO determines that a non-negative test result or other occurrence is an FFD policy violation, the MRO shall immediately notify the licensee's or other entity's designated representative.

(d) Donor unavailability. The MRO may determine that a non-negative test result or other occurrence is an FFD policy violation without having discussed the test result or other occurrence directly with the donor in the following three circumstances:

(1) The MRO has made and documented contact with the donor and the donor expressly declined the opportunity to discuss the test result or other occurrence that may constitute an FFD policy violation;

(2) A representative of the licensee or other entity, or an MRO staff member, has successfully made and documented contact with the donor and has instructed him or her to contact the MRO, and more than one business day has elapsed since the date on which the licensee's representative or MRO's staff member successfully contacted the donor; or

(3) The MRO, after making all reasonable efforts and documenting the dates and time of those efforts, has been unable to contact the donor. Reasonable efforts include, at a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the donor at the day and evening telephone numbers listed on the custody-and-control form.

(e) Additional opportunity for discussion. If the MRO determines that the donor has violated the FFD policy without having discussed the non-negative test result or other occurrence directly with the donor, the donor may, upon subsequent notification of the MRO determination and within 30 days of that notification, present to the MRO information documenting the circumstances, including, but not limited to, serious illness or injury, which unavoidably prevented the donor from being contacted by the MRO or a representative of the licensee or other entity, or from contacting the MRO in a timely manner. On the basis of this information, the MRO may reopen the procedure for determining whether the donor's test result or other occurrence is an FFD policy violation and permit the individual to present information related to the issue. The MRO may modify the initial determination based on an evaluation of the information provided.

(f) Review of invalid specimens.

(1) If the HHS-certified laboratory reports an invalid result, the MRO shall consult with the laboratory to determine whether additional testing by another HHS-certified laboratory may

be useful in determining and reporting a drug-positive, adulterated, or substituted test result. If the MRO and the laboratory agree that further testing would be useful, the HHS-certified laboratory shall forward the specimen to a second laboratory for additional testing.

(2) If the MRO and the laboratory agree that further testing would not be useful and there is no technical explanation for the result, the MRO shall contact the donor and determine whether there is an acceptable medical explanation for the invalid result. If there is an acceptable medical explanation, the MRO shall report to the licensee or other entity that the test result is not an FFD policy violation, but that a negative test result was not obtained. If the medical reason for the invalid result is, in the opinion of the MRO, a temporary condition, the licensee or other entity shall collect a second urine specimen from the donor as soon as reasonably practical and rely upon the MRO's review of the test results from the second collection. The second specimen collected for the purposes of this paragraph may not be collected under direct observation. If the medical reason for the invalid result would similarly affect the testing of another urine specimen, the MRO may authorize an alternative method for drug testing. Licensees and other entities may not impose sanctions for an invalid test result due to a medical condition.

(3) If the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation for the invalid test result, the MRO shall require that a second collection take place as soon as practical under direct observation. The licensee or other entity shall rely upon the MRO's review of the test results from the directly observed collection.

(g) Review of dilute specimens.

(1) If the HHS-certified laboratory reports that a specimen is dilute and that drugs or drug metabolites were detected in the specimen at or above the cutoff levels specified in this part or the licensee's or other entity's more stringent cutoff levels, and the MRO determines that

there is no legitimate medical explanation for the presence of the drugs or drug metabolites in the specimen, the MRO shall determine that the drug test results are positive and that the donor has violated the FFD policy.

(2) If the MRO has reason to believe that the donor may have diluted a specimen in a subversion attempt, the MRO may require the laboratory to conduct confirmatory testing of the specimen at the LOD for any drugs or drug metabolites as long as each drug class is evaluated in accordance with §26.31(c)(1)(ii). For purposes of this paragraph, the following circumstances are the exclusive grounds constituting a reason to believe that the donor may have diluted the specimen in a subversion attempt:

(i) The donor has presented, at this or a previous collection, a urine specimen that the HHS-certified laboratory reported as being substituted, adulterated, or invalid to the MRO and the MRO determined that there is no adequate technical or medical explanation for the result;

(ii) The donor has presented a urine specimen of 30 mL or more that falls outside the required temperature range, even if a subsequent directly observed collection was performed; and

(iii) The collector observed conduct clearly and unequivocally indicating an attempt to dilute the specimen.

(3) If the dilute specimen was collected under direct observation as required under §26.69, the MRO may require the laboratory to conduct confirmatory testing at the LOD for any drugs or drug metabolites, as long as each drug class is evaluated in accordance with §26.31(c)(1)(ii).

(4) If the drugs detected in a dilute specimen are any opium, opiate, or opium derivative (e.g., morphine/codeine), or if the drugs or metabolites detected indicate the use of prescription or over-the-counter medications, before determining that the donor has violated the FFD policy under paragraph (a) of this section, the MRO or his/her designee, who shall also be a licensed

physician with knowledge of the clinical signs of drug abuse, shall conduct the clinical examination for abuse of these substances that is required in paragraph (j) of this section. An evaluation for clinical evidence of abuse is not required if the laboratory confirms the presence of 6-AM (i.e., the presence of this metabolite is proof of heroin use) in the dilute specimen.

(h) Review of substituted specimens.

(1) If the HHS-certified laboratory reports a specimen as substituted (i.e., the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200), the MRO shall contact the donor and offer the donor an opportunity to provide a legitimate medical explanation for the substituted result. The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the specimen for which the HHS-certified laboratory reported a substituted result. Any medical evidence must be submitted through a referral physician who is experienced and qualified in the medical issues involved. Claims of excessive hydration, or claims based upon unsubstantiated personal characteristics, including, but not limited to, race, gender, diet, and body weight, are not acceptable evidence without medical studies which demonstrate that the donor did produce the laboratory result.

(2) If the MRO determines that there is no legitimate medical explanation for the substituted test result, the MRO shall report to the licensee or other entity that the specimen was substituted.

(3) If the MRO determines that there is a legitimate medical explanation for the substituted test result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity that no FFD policy violation has occurred.

(i) Review of adulterated specimens.

(1) If the HHS-certified laboratory reports a specimen as adulterated with a specific substance, the MRO shall contact the donor and offer the donor an opportunity to provide a

legitimate medical explanation for the adulterated result. The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the adulterated result through normal human physiology. Any medical evidence must be submitted through a referral physician experienced and qualified in the medical issues involved.

(2) If the MRO determines there is no legitimate medical explanation for the adulterated test result, the MRO shall report to the licensee or other entity that the specimen is adulterated.

(3) If the MRO determines that there is no legitimate medical explanation for the adulterated test result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity that no FFD policy violation has occurred.

(j) Review for opiates, prescription and over-the-counter medications.

(1) If the MRO determines that there is no legitimate medical explanation for a positive confirmatory test result for opiates and before the MRO determines that the test result is a violation of the FFD policy, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall determine that there is clinical evidence, in addition to the positive test result, that the donor has illegally used opium, an opiate, or an opium derivative (e.g., morphine/codeine). This requirement does not apply if the laboratory confirms the presence of 6-AM (i.e., the presence of this metabolite is proof of heroin use), or the morphine or codeine concentration is equal to or greater than 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. The MRO may not determine that the consumption of food products is a legitimate medical explanation for the presence of morphine or codeine at or above this concentration.

(2) If the MRO determines that there is no legitimate medical explanation for a positive test result for drugs other than opiates that are commonly prescribed or included in over-the-counter preparations (e.g., benzodiazepines in the first case, barbiturates in the second) and are listed in the licensee's or other entity's panel of substances to be tested, the MRO shall determine whether there is clinical evidence, in addition to the positive test result, of abuse of any of these substances or their derivatives.

(3) If the MRO determines that the donor has used another individual's prescription medication, including a medication containing opiates, and no clinical evidence of drug abuse is found, the MRO shall report to the licensee or other entity that the donor has misused a prescription medication. If the MRO determines that the donor has used another individual's prescription medication and clinical evidence of drug abuse is found, the MRO shall report to the licensee that the donor has violated the FFD policy.

(4) In determining whether a legitimate medical explanation exists for a positive test result for opiates, prescription or over-the-counter medications, the MRO may consider the use of a medication from a foreign country. The MRO shall exercise professional judgment consistently with the following principles:

(i) There can be a legitimate medical explanation only with respect to a drug that is obtained legally in a foreign country;

(ii) There can be a legitimate medical explanation only with respect to a drug that has a legitimate medical use. Use of a drug of abuse (e.g., heroin, PCP) or any other substance that cannot be viewed as having a legitimate medical use can never be the basis for a legitimate medical explanation, even if the drug is obtained legally in a foreign country; and

(iii) Use of the drug can form the basis of a legitimate medical explanation only if it is used consistently with its proper and intended medical purpose.

(5) The MRO may not consider consumption of food products, supplements, or other preparations containing substances that may result in a positive drug test result, including, but not limited to supplements containing hemp products or coca leaf tea, as a legitimate medical explanation for the presence of drugs or drug metabolites in the urine specimen above the cutoff levels specified in §26.163 or a licensee's or other entity's more stringent cutoff levels.

(6) The MRO may not consider the use of any drug contained in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812] as a legitimate medical explanation for a positive confirmatory drug test result, even if the drug may be legally prescribed and used under State law.

(k) Results consistent with legitimate drug use. If the MRO determines that there is a legitimate medical explanation for a positive drug test result, and that the use of a drug 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 the donor has not violated the licensee's or other entity's FFD policy. The MRO shall report to the licensee or other entity that no FFD policy violation has occurred. The MRO shall further evaluate the positive test result and medical explanation to determine whether use of the drug and/or the medical condition poses a potential risk to public health and safety as a result of the individual being impaired while on duty. If the MRO determines that such a risk exists, he or she shall ensure that a determination of fitness is performed.

(l) Retesting authorized. Should any question arise as to the accuracy or validity of a non-negative test result, only the MRO is authorized to order retesting of an aliquot of the original specimen. Retesting must be performed by a second HHS-certified laboratory. The MRO is also the only individual who may authorize a reanalysis of an aliquot of the original specimen or an analysis of any split specimen (Bottle B) in response to a written request from the donor tested.

(m) Result scientifically insufficient. Based on the review of inspection and audit reports, quality control data, multiple specimens, and other pertinent results, the MRO may determine that a non-negative test result is scientifically insufficient for further action and may declare that a drug or validity test result is not an FFD policy violation, but that a negative test result was not obtained. In this situation, the MRO may request retesting of the original specimen before making this decision. The MRO is neither expected nor required to request such retesting, unless in the sole opinion of the MRO, such retesting is warranted. The MRO may request that the reanalysis be performed by the same laboratory, or that an aliquot of the original specimen be sent for reanalysis to another HHS-certified laboratory. The licensee testing facility and the HHS-certified laboratory shall assist in this review process, as requested by the MRO, by making available the individual(s) responsible for day-to-day management of the licensee testing facility or 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 MRO.

(n) Evaluating results from a second laboratory. After a second laboratory tests an aliquot of a single specimen or the split (Bottle B) specimen, the MRO shall take the following actions if the second laboratory reports the following results:

(1) If the second laboratory reconfirms any drug-positive test results, the MRO may report an FFD policy violation to the licensee or other entity;

(2) If the second laboratory reconfirms any non-negative validity test results, the MRO may report an FFD policy violation to the licensee or other entity;

(3) If the second laboratory does not reconfirm the drug-positive test results, the MRO shall report that no FFD policy violation has occurred; or

(4) If the second laboratory does not reconfirm the non-negative validity test results, the MRO shall report that no FFD policy violation has occurred.

(o) Re-authorization after a first violation for a drug-positive test result. The MRO is responsible for reviewing drug test results from an individual whose authorization was terminated or denied for a first violation of the FFD policy involving a confirmed positive drug test result and who is being considered for re-authorization. In order to determine whether subsequent positive confirmatory drug test results represent new drug use or remaining metabolites from the drug use that initially resulted in the FFD policy violation, the MRO shall request from the HHS-certified laboratory, and the laboratory shall provide, quantitation of the test results and other information necessary to make the determination. If the drug for which the individual first tested positive was marijuana and the confirmatory assay for delta-9-tetrahydrocannabinol-9-carboxylic acid yields a positive result, the MRO shall determine whether the confirmatory test result indicates further marijuana use since the first positive test result, or whether the test result is consistent with the level of delta-9-tetrahydrocannabinol-9-carboxylic acid that would be expected if no further marijuana use had occurred. If the test result indicates that no further marijuana use has occurred since the first positive test result, then the MRO shall declare the drug test result as negative.

(p) Time to complete MRO review. The MRO shall complete his or her review of non-negative test results and, in those instances in which the MRO determines that the donor has violated the licensee's or other entity's FFD policy, notify licensee or other entity's designated representative within 10 days of an initial non-negative test result. The MRO shall notify the licensee or other entity of the FFD policy violation in writing and in a manner designed to ensure the confidentiality of the information.

§26.187 Substance abuse expert.

(a) Implementation. By **[insert date 2 years after publication of the final rule in the Federal Register]**, substance abuse experts (SAEs) upon whom licensees and other entities

rely to make determinations of fitness under this part shall meet the requirements of this section.

(b) Credentials. An SAE shall have at least one of the following credentials:

(1) A licensed physician;

(2) A licensed or certified social worker;

(3) A licensed or certified psychologist;

(4) A licensed or certified employee assistance professional; or

(5) An alcohol and drug abuse counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC) or by the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse (ICRC).

(c) Basic knowledge. An SAE shall be knowledgeable in the following areas:

(1) Demonstrated knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled-substance abuse disorders;

(2) Knowledge of the SAE function as it relates to the public's interests in the job duties performed by individuals who are subject to this part; and

(3) Knowledge of this part and any changes thereto.

(d) Qualification training. SAEs shall receive qualification training on the following subjects:

(1) Background, rationale, and scope of this part;

(2) Key drug testing requirements of this part, including specimen collection, laboratory testing, MRO review, and problems in drug testing;

(3) Key alcohol testing requirements of this part, including specimen collection, the testing process, and problems in alcohol tests;

(4) SAE qualifications and prohibitions;

(5) The role of the SAE in making determinations of fitness and the return-to-duty process, including the initial evaluation, referrals for education and/or treatment, the followup evaluation, continuing treatment recommendations, and the followup testing plan;

(6) Procedures for SAE consultation and communication with licensees or other entities, MROs, and treatment providers;

(7) Reporting and recordkeeping requirements of this part; and

(8) Issues that SAEs confront in carrying out their duties under this part.

(e) Continuing education. During each 3-year period following completion of initial qualification training, the SAE shall complete continuing education consisting of at least 12 continuing professional education hours relevant to performing SAE functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in SAE practice pertaining to this part, since the time the SAE met the qualification training requirements of this section.

(2) Continuing education activities must include documented assessment tools to assist in determining that the SAE has learned the material.

(f) Documentation. The SAE shall maintain documentation showing that he or she currently meets all requirements of this section. The SAE shall provide this documentation upon request to NRC representatives, licensees, or other entities who are relying upon or contemplating relying upon the SAE's services.

(g) Responsibilities and prohibitions. The SAE shall evaluate individuals who have violated the substance abuse provisions of an FFD policy and make recommendations concerning education, treatment, return to duty, followup drug and alcohol testing, and

aftercare. The SAE is not an advocate for the licensee or other entity, or the individual. The SAE's function is to protect public health and safety and the common defense and security by professionally evaluating the individual and recommending appropriate education/treatment, follow-up tests, and aftercare.

(1) The SAE is authorized to make determinations of fitness in at least the following three circumstances:

(i) When potentially disqualifying FFD information has been identified regarding an individual who has applied for authorization under this part;

(ii) When an individual has violated the substance abuse provisions of a licensee's or other entity's FFD policy; and

(iii) When an individual may be impaired by alcohol, prescription or over-the-counter medications, or illegal drugs.

(2) Upon determining the best recommendation for assisting the individual, the SAE shall serve as a referral source to assist the individual's entry into an education and/or treatment program.

(i) To prevent the appearance of a conflict of interest, the SAE may not refer an individual requiring assistance to his or her private practice or to a person or organization from whom the SAE receives payment or in which the SAE has a financial interest. The SAE is precluded from making referrals to entities with whom the SAE is financially associated.

(ii) There are four exceptions to the prohibitions contained in the preceding paragraph. The SAE may refer an individual to any of the following providers of assistance, regardless of his or her relationship with them:

(A) A public agency (e.g., treatment facility) operated by a state, county, or municipality;

(B) A person or organization under contract to the licensee or other entity to provide alcohol or drug treatment and/or education services (e.g., the licensee's or other entity's contracted treatment provider);

(C) The sole source of therapeutically appropriate treatment under the individual's health insurance program (e.g., the single substance abuse in-patient treatment program made available by the individuals' insurance coverage plan); or

(D) The sole source of therapeutically appropriate treatment reasonably available to the individual (e.g., the only treatment facility or education program reasonably located within the general commuting area).

§26.189 Determination of fitness.

(a) A determination of fitness is the process whereby it is determined whether there are indications that an individual may be in violation of the licensee's or other entity's FFD policy or is otherwise unable to safely and competently perform his or her duties. A determination of fitness must be made by a licensed or certified professional who is appropriately qualified and has the necessary clinical expertise, as verified by the licensee or other entity, to evaluate the specific fitness issues presented by the individual. A professional called upon by the licensee or other entity may not perform a determination of fitness regarding fitness issues that are outside of his or her specific areas of expertise. The types of professionals and the fitness issues for which they are qualified to make determinations of fitness include, but are not limited to, the following:

(1) An SAE who meets the requirements of §26.187 may determine the fitness of an individual who may have engaged in substance abuse and shall determine an individual's fitness to be granted authorization following an unfavorable termination or denial of authorization under this part, but may not be qualified to assess the fitness of an individual who

may have experienced mental illness, significant emotional stress, or other mental or physical conditions that may cause impairment but are unrelated to substance abuse, unless the SAE has additional qualifications for addressing those fitness issues;

(2) A clinical psychologist may determine the fitness of an individual who may have experienced mental illness, significant emotional stress, or cognitive or psychological impairment from causes unrelated to substance abuse, but may not be qualified to assess the fitness of an individual who may have a substance abuse disorder, unless the psychologist is also an SAE;

(3) A psychiatrist may determine the fitness of an individual who is taking psychoactive medications in accordance with one or more valid prescription(s), but may not be qualified to assess potential impairment attributable to substance abuse, unless the psychiatrist has had specific training to diagnose and treat substance abuse disorders;

(4) A physician may determine the fitness of an individual who may be ill, injured, fatigued, taking medications in accordance with one or more valid prescriptions, or using over-the-counter medications, but may not be qualified to assess the fitness of an individual who may have a substance abuse disorder, unless the physician is also an SAE; and

(5) As a physician with specialized training, the MRO may determine the fitness of an individual who may have engaged in substance abuse or may be ill, injured, fatigued, taking medications in accordance with one or more valid prescriptions, and/or using over-the-counter medications, but may not be qualified to assess an individual's fitness to be granted authorization following an unfavorable termination or denial of authorization under this part, unless the MRO is also an SAE.

(b) A determination of fitness must be made in at least the following circumstances:

(1) When there is an acceptable medical explanation for a non-negative test result, but there is a basis for believing that the individual could be impaired while on duty;

(2) Before making return-to-duty recommendations after an individual's authorization has been terminated unfavorably or denied in accordance with a licensee's or other entity's FFD policy;

(3) Before an individual is granted authorization when potentially disqualifying FFD information is identified and has not previously been evaluated by another licensee or entity who is subject to this part; and

(4) When potentially disqualifying FFD information is otherwise identified and the licensee's or other entity's reviewing official concludes that a determination of fitness is warranted under §26.69.

(c) A determination of fitness that is conducted "for cause" must be conducted through face-to-face interaction between the subject individual and the professional making the determination. Electronic means of communication may not be used.

(1) If there is neither conclusive evidence of an FFD policy violation nor a significant basis for concern that the individual may be impaired while on duty, then the individual must be determined to be fit for duty.

(2) If there is no conclusive evidence of an FFD policy violation but there is a significant basis for concern that the individual may be impaired while on duty, then the subject individual must be determined to be unfit for duty. This result does not constitute a violation of this part nor of the licensee's or other entity's FFD policy, and no sanctions may be imposed. However, the professional who made the determination of fitness shall consult with the licensee's or other entity's management personnel to identify the actions required to ensure that any possible limiting condition does not represent a threat to workplace or public health and safety. Licensee or other entity management personnel shall implement the required actions. When appropriate, the subject individual may also be referred to the EAP.

(d) Neither the individual nor licensees and other entities may seek a second determination of fitness if a determination of fitness under this part has already been performed by a qualified professional employed by or under contract to the licensee or other entity. After the initial determination of fitness has been made, the professional may modify his or her evaluation and recommendations based on new or additional information from other sources including, but not limited to, the subject individual, another licensee or entity, or staff of an education or treatment program. Unless the professional who made the initial determination of fitness is no longer employed by or under contract to the licensee or other entity, only that professional is authorized to modify the evaluation and recommendations. When reasonably practicable, licensees and other entities shall assist in arranging for consultation between the new professional and the professional who is no longer employed by or under contract to the licensee or other entity, to ensure continuity and consistency in the recommendations and their implementation.

Subpart I – Managing Fatigue.

§26.195 Applicability.

The requirements in this subpart apply only to the licensees and other entities identified in §26.3(a) and (d).

§26.197 General provisions.

(a) Policy. Licensees shall establish a policy for the management of fatigue and incorporate it into the written policy required in §26.27(b).

(b) Procedures. In addition to the procedures required in §26.27(c), licensees shall develop, implement, and maintain procedures that —

(1) Describe the process to be followed when any individual who is subject to an FFD program under §26.25(a)(1) or (2) makes a self-declaration that he or she is not fit to safely and competently perform his or her duties for any part of a working tour as a result of fatigue. The procedure must —

(i) Describe the individual's and licensee's responsibilities related to self-declaration;

(ii) Describe requirements for establishing controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit due to fatigue; and

(iii) Describe the process to be followed if the individual disagrees with the results of a fatigue assessment that is required under §26.201(a)(2);

(2) Describe the process for implementing the work hour controls required under §26.199 for the individuals who are performing the duties listed in §26.199(a);

(3) Describe the process to be followed in conducting fatigue assessments under §26.201; and

(4) Describe the sanctions, if any, that the licensee may impose on an individual following a fatigue assessment.

(c) Training and examinations. Licensees shall add the following KAs to the content of the training that is required in §26.29(a) and the comprehensive examination required in §26.29(b):

(1) Knowledge of the contributors to worker fatigue, circadian variations in alertness and performance, indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures; and

(2) Ability to identify symptoms of worker fatigue and contributors to decreased alertness in the workplace.

(d) Recordkeeping. Licensees shall retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later:

(1) Records of work hours for individuals who are subject to the work hour controls in §26.199;

(2) The documentation of waivers that is required in §26.199(d)(3)(iv), including the bases for granting the waivers;

(3) The documentation of work hour reviews that is required in §26.199(j)(3);

(4) The documentation of fatigue assessments that is required in §26.201(g); and

(5) Documentation of the collective work hours of each job duty group, as calculated in accordance with §26.199(b)(2).

(e) Reporting. Licensees shall include the following information in the annual FFD program performance report required under §26.217:

(1) A summary of the number of instances during the previous calendar year in which the licensee waived any of the work hour controls specified in §26.199(d)(1) and (d)(2) for individuals within each job duty group in §26.199(a). The report must include —

(i) Only those waivers under which work was performed; and

(ii) Each work hour control that was waived in §26.199(d)(1) and (d)(2), including all of the work hour controls that were waived for any single extended work period for which it was necessary to waive more than one work hour control;

(2) The collective work hours of any job duty group listed in §26.199(a) that exceeded an average of 48 hours per person per week in any averaging period during the previous calendar year, in accordance with §26.199(f)(3) and (f)(5). The report must also include —

(i) The dates that defined the averaging period(s) during which collective work hours exceeded 48 hours per person per week;

(ii) The job duty group that exceeded the collective work hours limit; and

(iii) The conditions that caused the job duty group's collective work hours to exceed the collective work hours limit; and

(3) The number of fatigue assessments conducted during the previous calendar year, the conditions under which each fatigue assessment was conducted (i.e., self-declaration, for cause, post-event, followup), and the management actions, if any, resulting from each fatigue assessment.

§26.199 Work hour controls.

(a) Individuals subject to work hour controls. Any individual who performs duties within the following job duty groups is subject to the requirements of this section:

(1) Operating or on-site directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health and safety;

(2) Performing maintenance or on-site directing of the maintenance of structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety;

(3) Performing Health Physics or Chemistry duties required as a member of the on-site emergency response organization minimum shift complement;

(4) Performing the duties of a Fire Brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability; and

(5) Performing security duties as an armed security force officer, alarm station operator, response team leader, or watchperson, hereinafter referred to as security personnel.

(b) Calculating work hours.

(1) Individual work hours. For the purposes of this subpart, licensees shall calculate an individual's work hours as the amount of time that an individual performs any duties for a licensee who is subject to this subpart, including all within-shift break times and rest periods during which there are no reasonable opportunities or accommodations appropriate for restorative sleep, but excluding shift turnover.

(i) Shift turnover includes only those activities that are necessary to safely transfer information and responsibilities between two or more individuals between shifts. Shift turnover activities may include, but are not limited to, discussions of the status of plant equipment, and the status of ongoing activities, such as extended tests of safety systems and components. Licensees may not exclude work hours worked during turnovers between individuals within a shift period due to rotations or relief within a shift. Activities that licensees may not exclude from work hours calculations also include, but are not limited to, shift holdovers to cover for late arrivals of incoming shift members; early arrivals of individuals for meetings, training, or pre-shift briefings for special evolutions; and holdovers for interviews needed for event investigations.

(ii) Other than shift turnover, only that portion of a break or rest period during which there is a reasonable opportunity and accommodations for restorative sleep may be excluded from the licensee's calculation of an individual's work hours.

(iii) Licensees need not calculate the work hours of an individual who is qualified to perform the job duties listed in paragraph (a) of this section but has not performed such duties during the applicable calculation period. However, if the individual begins or resumes performing any of the job duties listed in paragraph (a) of this section, the licensee shall include in the calculation of the individual's work hours all work hours worked, including hours worked

performing duties that are not listed in paragraph (a) of this section, and control the individual's work hours in accordance with the requirements of paragraph (d) of this section.

(2) Collective work hours. For the purposes of this subpart, licensees shall calculate collective work hours as the average number of work hours worked among each group of individuals who perform the duties listed in paragraph (a) of this section, within an averaging period that may not exceed 13 weeks, as follows:

(i) Licensees may define broad job duty groups comprised of individuals who perform the job duties listed in paragraph (a) of this section, or may define smaller groups of individuals who perform similar duties. The groups must collectively include all individuals who perform the job duties listed in paragraph (a) of this section;

(ii) Licensees shall include in the average for each job duty group the work hours of any individual who performs the job duties of the group at the licensee's site, except if, during the averaging period the individual worked less than 75 percent of the group's normally scheduled hours;

(iii) The days included in an averaging period must be consecutive or separated only by days that licensees are permitted to exclude from the collective work hour calculation under §26.199(f)(1) through (f)(3) and (f)(5), (h), and (i);

(iv) Licensees shall include within an averaging period all days that are not excluded from collective work hour controls under §26.199(f)(1) through (f)(3) and (f)(5), (h), and (i); and

(v) Licensees may not include in the collective work hour calculation for an averaging period any work hours that are included in a collective work hour calculation for any other averaging period.

(c) Work hours scheduling. Licensees shall schedule the work hours of individuals who are subject to this section consistent with the objective of preventing impairment from fatigue due to the duration, frequency, or sequencing of successive shifts.

(d) Work hour controls for individuals. Licensees shall control the work hours of individuals, as follows:

(1) Except as permitted under paragraph (d)(3) of this section, licensees shall ensure that any individual's work hours do not exceed the following limits:

(i) 16 work hours in any 24-hour period;

(ii) 26 work hours in any 48-hour period; and

(iii) 72 work hours in any 7-day period.

(2) Licensees shall ensure that individuals have adequate rest breaks. For the purposes of this subpart, a break is defined as an interval of time that falls between successive work periods, during which the individual does not perform any duties for the licensee other than shift turnover. At a minimum, licensees shall ensure that individuals who are subject to this section have the following breaks:

(i) A 10-hour break between successive work periods or an 8-hour break between successive work periods when a break of less than 10 hours is necessary to accommodate a crew's scheduled transition between work schedules or shifts;

(ii) A 24-hour break in any 7-day period; and

(iii) A 48-hour break in any 14-day period, except during the first 14 days of any plant outage if the individual is performing the job duties listed in paragraph (a)(1) through (a)(4) of this section.

(3) Licensees may grant a waiver of the individual work hour controls in paragraphs (d)(1) and (d)(2) of this section, as follows:

(i) In order to grant a waiver, the licensee shall meet both of the following requirements:

(A) An operations shift manager determines that the waiver is necessary to mitigate or prevent a condition adverse to safety, or a security shift manager determines that the waiver is

necessary to maintain the security of the facility, or a site senior-level manager with requisite signature authority makes either determination; and

(B) A supervisor, who is qualified to direct the work to be performed by the individual and trained in accordance with the requirements of §§26.29 and 26.197(c), assesses the individual face to face and determines that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted. At a minimum, the assessment must address the potential for acute and cumulative fatigue considering the individual's work history for at least the past 14 days, the potential for circadian degradations in alertness and performance considering the time of day for which the waiver will be granted, the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions, and whether any controls and conditions must be established under which the individual will be permitted to perform work;

(ii) To the extent practicable, licensees shall rely upon the granting of waivers only to address circumstances that could not have been reasonably controlled;

(iii) Licensees shall ensure that the timing of the face-to-face supervisory assessment that is required in paragraph (d)(3)(i)(B) of this section supports a valid assessment of the potential for worker fatigue during the time the individual will be performing work under the waiver. Licensees may not perform the face-to-face assessment more than four hours before the individual begins performing any work under the waiver; and

(iv) Licensees shall document the bases for individual waivers. The documented basis for a waiver must include a description of the circumstances that necessitate the waiver, a statement of the scope of work and time period for which the waiver is approved, and the bases for the determinations required in paragraph (d)(3)(i) of this section.

(e) <u>Self-declarations during extended work hours</u>. If an individual is performing, or being assessed for, work under a waiver of the requirements contained in paragraphs (d)(1) and

(d)(2) of this section and declares that, due to fatigue, he or she is unable to safely and competently perform his or her duties, the licensee shall immediately stop the individual from performing any duties listed in paragraph (a) of this section, except if the individual is required to continue performing those duties under other requirements of this chapter. If the subject individual must continue performing the duties listed in paragraph (a) of this section until relieved, the licensee shall immediately take action to relieve the individual. Following the self-declaration or relief from performing the duties listed in paragraph (a) of this section, as applicable, the licensee —

(1) May reassign the individual to duties other than those listed in paragraph (a) of this section, but only if the results of a fatigue assessment, conducted in accordance with the requirements of §26.201, indicate that the individual is fit to safely and competently perform those other duties; and

(2) Shall permit or require the individual to take a rest break of at least 10 hours before the individual returns to performing any duties listed in paragraph (a) of this section.

(f) Collective work hour limits. In addition to controlling individuals' work hours in accordance with paragraph (d) of this section, licensees shall control the collective work hours of each group of individuals who are performing similar job duties, as listed in paragraph (a) of this section. Licensees shall ensure that the collective work hours of each job duty group do not exceed an average of 48 hours per person per week in any averaging period, except as follows:

(1) The licensee need not impose the collective work hour controls required in this paragraph on the job duty groups specified in paragraphs (a)(1) through (a)(4) of this section during the first 8 weeks of a plant outage;

(2) For job duty groups comprised of security personnel —

(i) The group work hour average(s) may not exceed 60 hours per person per week during the first 8 weeks of a plant outage or a planned security system outage;

(ii) The group work hour average(s) may not exceed 60 hours per person per week during the actual conduct of force-on-force tactical exercises (i.e., licensee exercises and NRC-observed exercises);

(iii) The licensee need not impose any collective work hour controls for the first 8 weeks of an unplanned security system outage or an increased threat condition;

(iv) If an increase in threat condition occurs while the site is in any plant outage or a planned security system outage and the increased threat condition persists for a period of 8 weeks or less, the licensee need not impose collective work hour controls on security personnel for the duration of the increased threat condition. However, if during any such outage, the threat condition returns to the least significant threat condition that was in effect at any time within the past 8 weeks, then the licensee shall limit the collective work hours of security personnel to an average of 60 hours per person per week for the first 8 weeks of the outage for the periods prior to and following the increased threat condition, and shall limit the collective work hours of security personnel to an average of 48 hours per person per week following the first 8 weeks of the outage;

(v) If additional increases in threat condition occur during an unplanned security system outage or increased threat condition, the relaxation of the collective work hour limits that is permitted in paragraph (f)(2)(iii) of this section may be extended with each increase in the threat condition, but only for a period that is the shorter of either the duration of the increased threat condition or 8 weeks;

(vi) If the threat condition decreases during an unplanned security system outage or increased threat condition, the applicability of the relaxation of the collective work hour limits

that is permitted in paragraph (f)(2)(iii) of this section must based upon the date upon which the current threat condition was last entered as a result of an increase;

(3) The collective work hours of any job duty group listed in paragraph (a) of this section may exceed an average of 48 hours per person per week in one averaging period if all of the following conditions are met:

(i) The circumstances that cause the group's collective work hours to exceed 48 hours per person per week cannot be reasonably controlled;

(ii) The group's collective work hours do not exceed 54 hours per person per week; and

(iii) The additional work hours that result in the group's collective work hours exceeding 48 hours per person per week are worked only to address the circumstances that the licensee could not have reasonably controlled.

(4) The collective work hours of any job duty group may not exceed 48 hours per person per week if the collective work hours for the job duty group exceeded 48 hours per person per week —

(i) In the previous averaging period; or

(ii) In any other averaging period that ended within the past 26 weeks.

(5) Licensees may also exceed any collective work hour limits in this paragraph if the licensee has received prior approval from the NRC of a written request that includes, at a minimum, —

(i) A description of the specific circumstances that require the licensee to exceed the applicable collective work hour limit, the job duty group(s) affected, and the collective work hours limit(s) to be exceeded;

(ii) A statement of the period of time during which it will be necessary to exceed the collective work hour limit(s); and

(iii) A description of the fatigue mitigation strategies, including, but not limited to, rest break requirements and work hour limits, that the licensee will implement to ensure that the individuals affected will be fit to safely and competently perform their duties.

(g) Successive plant outages. If two or more plant outages occur at the licensee's site and the interval(s) between successive outages is less than 2 weeks, the licensee shall apply the requirements in paragraphs (d)(2)(iii), (f)(1), (f)(2)(i), and (f)(2)(iv) of this section based upon the number of days that have elapsed since the first plant outage in the series began.

(h) Common defense and security. Licensees need not meet the requirements of this section when informed in writing by the NRC that these requirements, or any subset thereof, are waived for security personnel in order to assure the common defense and security, for the duration of the period defined by the NRC.

(i) Plant emergencies. Licensees need not meet the requirements of paragraphs (c) through (f) of this section during declared emergencies, as defined in the licensee's emergency plan.

(j) Reviews. Licensees shall review the control of work hours for individuals who are subject to this subpart for each averaging period. Licensees shall complete this review within 30 days of the end of the averaging period. If any outages or increased threat conditions occurred since the licensee completed the most recent review, the licensee shall include in the review an assessment of the control of work hours during the outages or increased threat conditions. Licensees shall —

(1) Review the work hours and performance of individuals to assess the effectiveness of the licensee's work hour controls in achieving the objective of reasonable assurance that fatigue due to work hours does not compromise individuals' abilities to safely and competently perform their duties. At a minimum, the licensee's review must address —

(i) Individuals who were granted more than one waiver during the review period;

(ii) Individuals who were assessed for fatigue in accordance with §26.201 during the review period;

(iii) Individuals who performed the job duties listed in paragraph (a) of this section whose average work hours per week exceeded 54 hours during any averaging period for which the collective work hour limit is 48 hours in this section; and

(iv) Any security personnel whose average work hours per week exceeded 66 hours in any averaging periods for which the collective work hours limit in this section is 60 hours per person per week;

(2) Review individuals' hours worked and the waivers under which work was performed to assess staffing adequacy for all jobs subject to the work hour controls of this section;

(3) Document the methods used to conduct these reviews and the results of the reviews; and

(4) Record, trend, and correct, under the licensee's corrective action program, any problems identified in maintaining control of work hours consistent with the specific requirements and performance objectives of this part.

§26.201 Fatigue Assessments.

(a) Licensees shall ensure that fatigue assessments are conducted under the following conditions:

(1) For-cause. In addition to any other test or determination of fitness that may be required under §§26.31(c) and 26.77, a fatigue assessment must be conducted in response to an observed condition of impaired individual alertness creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties, except if the condition is observed during an individual's break period. If the observed condition is impaired alertness

with no other behaviors or physical conditions creating a reasonable suspicion of possible substance abuse, then the licensee need only conduct a fatigue assessment. If the licensee has reason to believe that the observed condition is not due to fatigue, the licensee need not conduct a fatigue assessment;

(2) Self-declaration. A fatigue assessment must be conducted in response to an individual's self-declaration to his or her supervisor that he or she is not fit to safely and competently perform his or her duties for any part of a working tour because of fatigue, except if, following the self-declaration, the licensee permits or requires the individual to take a rest break of at least 10 hours before the individual returns to duty;

(3) Post-event. A fatigue assessment must be conducted in response to events requiring post-event drug and alcohol testing as specified in §26.31(c). Licensees may not delay necessary medical treatment in order to conduct a fatigue assessment; and

(4) Followup. If a fatigue assessment was conducted for cause or in response to a self-declaration, and the licensee returns the individual to duty following a rest break of less than 10 hours in duration, the licensee shall reassess the individual for fatigue as well as the need to implement controls and conditions before permitting the individual to resume performing any job duties.

(b) Either a supervisor or a staff member of the FFD program, who is trained in accordance with the requirements of §26.29 and §26.197(c), shall conduct the fatigue assessment face to face with the individual whose alertness may be impaired.

(1) In the case of a fatigue assessment conducted for cause, the individual who observed the condition of impaired alertness may not conduct the fatigue assessment.

(2) In the case of a post-event fatigue assessment, the individual who conducts the fatigue assessment may not have —

(i) Performed or directed the work activities during which the event occurred;

(ii) Performed, within 24 hours before the event occurred, a fatigue assessment of the individuals who were performing or directing the work activities during which the event occurred; and

(iii) Evaluated or approved a waiver of the limits specified in §26.199(d)(1) and (2) for any of the individuals who were performing or directing the work activities during which the event occurred, if the event occurred while such individuals were performing work under that waiver.

(c) A fatigue assessment must provide the information necessary for management decisions and actions in response to the circumstance that initiated the assessment.

(1) At a minimum, the fatigue assessment must address the following factors:

(i) Acute fatigue;

(ii) Cumulative fatigue; and

(iii) Circadian variations in alertness and performance.

(2) Individuals shall provide complete and accurate information that may be required by the licensee to address the factors listed in paragraph (c)(1) of this section. Licensees shall limit any inquiries to obtaining from the subject individual only the personal information that may be necessary to assess the factors listed in paragraph (c)(1) of this section.

(d) The licensee may not conclude that fatigue had not or will not degrade the individual's ability to safely and competently perform his or her duties solely on the basis that the individual's work hours have not exceeded any of the limits specified in §26.199(d)(1) or that the individual has had the minimum rest breaks required in §26.199(d)(2), as applicable.

(e) Following a fatigue assessment, the licensee shall determine and implement the controls and conditions, if any, that are necessary to permit the individual to resume performing duties for the licensee, including the need for a rest break.

(f) Licensees shall document the results of any fatigue assessments conducted, the circumstances that necessitated the fatigue assessment, and any controls and conditions that were implemented.

Subpart J - Recordkeeping and Reporting Requirements

§26.211 General provisions.

(a) Each licensee and other entity who is subject to this part shall maintain records and submit certain reports to the NRC. Records that are required by the regulations in this part must be retained for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility's license, certificate, or other regulatory approval.

(b) All records may be stored and archived electronically, provided that the method used to create the electronic records meets the following criteria:

(1) Provides an accurate representation of the original records;

(2) Prevents the alteration of any archived information and/or data once it has been committed to storage; and

(3) Permits easy retrieval and re-creation of the original records.

§26.213 Recordkeeping requirements for licensees and other entities.

(a) Each licensee and other entity who is subject to this part shall retain the following records for at least 5 years after the licensee or other entity terminates or denies an individual's authorization or until the completion of all related legal proceedings, whichever is later:

(1) Records of self-disclosures, employment histories, and suitable inquiries that are required under §§26.55, 26.57, 26.59, and 26.69 that result in the granting of authorization;

(2) Records pertaining to the determination of a violation of the FFD policy and related management actions;

(3) Documentation of the granting and termination of authorization; and

(4) Records of any determinations of fitness conducted under §26.189.

(b) Each licensee and other entity who is subject to this part shall retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later:

(1) Records of FFD training and examinations conducted under §26.29; and

(2) Records of audits, audit findings, and corrective actions taken under §26.41.

(c) Licensees and other entities shall ensure the retention and availability of records pertaining to any 5-year denial of authorization under §26.75(c), (d), or (e)(2) and any permanent denial of authorization under §26.75(b) and (g) for at least 40 years or until, upon application, the NRC determines that the records are no longer needed.

(d) Licensees and other entities shall retain any superseded versions of the written FFD policy and procedures required under §§26.27, 26.39, and 26.197(b) for at least 5 years or until completion of all legal proceedings related to an FFD violation that may have occurred under the policy and procedures, whichever is later.

(e) Licensees and other entities shall retain written agreements for the provision of services under this part for the life of the agreement or until completion of all legal proceedings related to an FFD policy violation that involved those services, whichever is later.

(f) Licensees and other entities shall retain records of the background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under §26.31(b)(1)(ii), for the length of the individual's employment by or contractual

relationship with the licensee or other entity, or until the completion of all related legal proceedings, whichever is later.

(g) If a licensee's or other entity's FFD program includes tests for drugs in addition to those specified in this part, as permitted under §26.31(d)(1), or uses more stringent cutoff levels than those specified in this part, as permitted under §26.31(d)(3), the licensee or other entity shall retain documentation certifying the scientific and technical suitability of the assays and cutoff levels used, as required under §26.31(d)(1)(i) and (d)(3)(iii)(C), respectively, for the period of time during which the FFD program follows these practices or until the completion of all related legal proceedings, whichever is later.

§26.215 Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services.

(a) Collection sites providing services to licensees and other entities, licensee testing facilities, and HHS-certified laboratories shall maintain and make available documentation of all aspects of the testing process for at least 2 years or until the completion of all legal proceedings related to a determination of an FFD violation, whichever is later. This 2-year period may be extended upon written notification by the NRC or by any licensee or other entity for whom services are being provided.

(b) Documentation that must be retained includes, but is not limited to, the following:

(1) Personnel files, including training records, for all individuals who have been authorized to have access to specimens, but are no longer under contract to or employed by the collection site, licensee testing facility, or HHS-certified laboratory;

(2) Chain-of-custody documents (other than forms recording specimens with negative test results and no FFD violations or anomalies, which may be destroyed after appropriate summary information has been recorded for program administration purposes);

(3) Quality assurance and quality control records;

(4) Superseded procedures;

(5) All test data (including calibration curves and any calculations used in determining test results);

(6) Test reports;

(7) Records pertaining to performance testing;

(8) Records pertaining to the investigation of 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 adversely reflect on the integrity of the testing process, investigation findings, and corrective actions taken, where applicable;

(9) Performance records on certification inspections;

(10) Records of preventative maintenance on licensee testing facility instruments;

(11) Records that summarize any test results that the MRO determined to be scientifically insufficient for further action;

(12) Either printed or electronic copies of computer-generated data;

(13) Records that document the dates, times of entry and exit, escorts, and purposes of entry of authorized visitors, maintenance personnel, and service personnel who have accessed secured areas of licensee testing facilities and HHS-certified laboratories; and

(14) Records of the inspection, maintenance, and calibration of EBTs.

§26.217 Fitness-for-duty program performance data.

(a) Licensees and other entities shall collect and compile FFD program performance data for each FFD program that is subject to this part.

(b) The FFD program performance data must include the following information:

(1) The random testing rate;

(2) Drugs for which testing is conducted and cutoff levels, including results of tests using lower cutoff levels and tests for drugs not included in the HHS panel;

(3) Populations tested (i.e., individuals in applicant status, permanent licensee employees, C/Vs);

(4) Number of tests administered and results of those tests sorted by population tested (i.e., individuals in applicant status, permanent licensee employees, C/Vs);

(5) Conditions under which the tests were performed, as defined in §26.31(c);

(6) Substances identified;

(7) Number of subversion attempts by type; and

(8) Summary of management actions.

(c) Licensees and other entities who have a licensee-approved FFD program shall analyze the data at least annually and take appropriate actions to correct any identified program weaknesses. Records of the data, analyses, and corrective actions taken must be retained for at least 3 years or until the completion of any related legal proceedings, whichever is later.

(d) Any licensee or other entity who terminates an individual's authorization or takes administrative action on the basis of the results of a positive initial drug test for marijuana or cocaine shall also report these test results in the annual summary by processing stage (i.e., initial testing at the licensee testing facility, testing at the HHS-certified laboratory, and MRO

determinations). The report must also include the number of terminations and administrative actions taken against individuals for the reporting period.

(e) Licensees and other entities shall submit the FFD program performance data (for January through December) to the NRC annually, before March 1 of the following year.

(f) Licensees and other entities may submit the FFD program performance data in a consolidated report, as long as the report presents the data separately for each site.

(g) Each C/V who maintains a licensee-approved drug and alcohol testing program is subject to the reporting requirements of this section and shall submit the required information either directly to the NRC or through the licensee(s) or other entities to whom the C/V provided services during the year. Licensees, other entities, and C/Vs shall share information to ensure that the information is reported completely and is not duplicated in reports submitted to the NRC.

§26.219 Reporting requirements.

(a) Required reports. Each licensee and entity who is subject to this part shall inform the NRC of significant violations of the FFD policy, significant FFD program failures, and errors in drug and alcohol testing. These events must be reported under this section, rather than under the provisions of 10 CFR 73.71.

(b) Significant FFD policy violations or programmatic failures. The following significant FFD policy violations and programmatic failures must be reported to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers the violation:

(1) The use, sale, distribution, possession, or presence of illegal drugs, or the consumption or presence of alcohol within a protected area;

(2) Any acts by any person licensed under 10 CFR Parts 52 and/or 55 to operate a power reactor, as well as any acts by SSNM transporters, FFD program personnel, or any supervisory personnel who are authorized under this part, if such acts —

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

(ii) Result in a determination that the individual has violated the licensee's or other entity's FFD policy (including subversion as defined in §26.5); or

(iii) Involve the consumption of alcohol within a protected area or while performing the job duties that require the individual to be subject to this part;

(3) Any intentional act that casts doubt on the integrity of the FFD program; and

(4) Any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals within a protected area, or by individuals who are assigned to perform job duties that require them to be subject to this part.

(c) Drug and alcohol testing errors.

(1) Within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered in blind performance testing at either a licensee testing facility or an HHS-certified laboratory, in the testing of actual specimens, or through the processing of reviews under §26.39 and MRO reviews under §26.185, as well as any other errors or matters that could adversely reflect on the integrity of the random selection or testing process, the licensee or other entity shall submit to the NRC a report of the incident and corrective actions taken or planned. If the error involves an HHS-certified laboratory, the NRC shall ensure that HHS is notified of the finding.

(2) Should a false positive error occur on a blind performance test sample submitted to an HHS-certified laboratory, the licensee or other entity shall notify the NRC within 24 hours after discovery of the error.

(3) Should a false negative error occur on a quality assurance check of validity screening devices, as required in §26.137(b)(2) and (3), the licensee or other entity shall notify the NRC within 24 hours after discovery of the error.

(d) Indicators of programmatic weaknesses. Licensees and other entities shall document, trend, and correct non-reportable indicators of FFD programmatic weaknesses under the licensee's or other entity's corrective action program, but may not track or trend drug and alcohol test results in a manner that would permit the identification of any individuals.

Subpart K – Inspections, Violations, and Penalties

§26.221 Inspections.

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

(b) Written agreements between licensees or other entities and their C/Vs must clearly show that —

(1) The licensee or other entity is responsible to the NRC for maintaining an effective FFD program in accordance with this part; and

(2) Duly authorized NRC representatives may inspect, copy, or take away copies of any licensee's, other entity's, or C/V's documents, records, and reports related to implementation of the licensee's or other entity's FFD program under the scope of the contracted activities.

§26.223 Violations.

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

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974; or

(3) Any regulation or order issued under these Acts.

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

(1) Section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act;

(2) Section 206 of the Energy Reorganization Act of 1974;

(3) Any rule, regulation, or order issued under these sections;

(4) Any term, condition, or limitation of any license issued under these sections; or

(5) Any provisions for which a license may be revoked under section 186 of the Atomic Energy Act of 1954.

§26.225 Criminal penalties.

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

(b) The regulations in Part 26 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§26.1, 26.3, 26.5, 26.7, 26.8, 26.9, 26.11, 26.51, 26.81, 26.121, 26.151, 26.181, 26.195, 26.223, and 26.225.

* * * * *

Dated at Rockville, Maryland, this ___ day of _____, 2005.

For the Nuclear Regulatory Commission.

_____

Annette Vietti-Cook,

Secretary of the Commission.

Appendix—Tables 1 and 2

Note: This appendix will not appear in The Code of Federal Regulations.

TABLE 1.—DERIVATION TABLE FOR PART 26

Note: The Proposed Rule constitutes a complete revision of Part 26. Substantial changes frequently have been made between the new section in the proposed rule and the derivation listed in Table 1.

New Section	Based on
26.1	26.1 first sentence
26.3(a)	26.2 (a)
26.3(b)	26.1 (2nd sentence) and 26.2 (a) (1st sentence)
26.3(c)	26.2(d)
26.3(d)	26.23 (a) (1)
26.3(e)	26.2 (c)
26.3(f)	26.2 (b)
26.5	26.3 and Appendix. A Subpart 1.2
26.7	26.4
26.8	26.8
26.9	26.6
26.11	NEW
26.21	26.23 (b)
26.23 (a)	26.10 (a)
26.23 (b)	26.10 (a)
26.23 (c)	26.10 (b)
26.23 (d)	26.10 (c)
26.23 (e)	NEW
26.25 (a) (1)	26.2 (a) and 26.2 (d)
26.25 (a) (2)	26.2 (a) and 26.2 (d)
26.25 (a) (3)	26.2 (a) and 26.2 (d)
26.25 (a) (4)	NEW
26.25 (b) (1)	NEW
26.25 (b) (2)	26.2 (b)
26.25 (b) (3)	26.2 (b)
26.25 (c)	NEW

New Section	Based on
26.25 (d)	NEW
26.27 (a)	26.20 1st paragraph
26.27 (b) (1)	26.20 (a)
26.27 (b) (2)	NEW
26.27 (b) (3)	NEW
26.27 (b) (4) (i)	26.20 (a) (1)
26.27 (b) (4) (ii)	26.20 (a) (2)
26.27 (b) (5)	NEW
26.27 (b) (6)	26.20 (a)
26.27 (b) (7)	26.20 (b)
26.27 (b) (8)	26.20 (d)
26.27 (b) (9)	NEW
26.27 (b) (10)	NEW
26.27 (b) (11)	NEW
26.27 (c)	26.20 (d)
26.29	26.21
26.31	26.24
26.33	26.22
26.35	26.25
26.37	26.29
26.39	26.27
26.41	26.80
26.51	26.1
26.53	NEW
26.55 (a)	26.27 (a)
26.55 (b)	NEW
26.57 (a)	NEW
26.57 (b)	NEW
26.59	NEW
26.61 (a)	26.27 (a) (1)
26.61 (b)	26.27 (a) (2)
26.61 (c)	NEW
26.61 (d)	26.27 (a) (4)
26.63 (a)	NEW
26.63 (b)	NEW
26.63 (c)	NEW
26.63 (d)	26.27 (a) (3)
26.63 (e)	NEW
26.63 (f) (1)	26.71 (c) and 26.27 (b) (2) (vii)
26.63 (f) (2)	NEW
26.63 (f) (3)	NEW
26.65 (a)	NEW
26.65 (b)	NEW
26.65 (c) (1)	26.24 (a) (1)
26.65 (c) (2)	NEW
26.65 (d)	NEW
26.65 (e)	NEW
26.65 (f)	NEW
26.65 (g)	NEW
26.65 (h)	Appendix A Subpart B 2.9 (c) and 26.27 (a) (2)

New Section	Based on
26.67 (a)	NEW
26.67 (b)	NEW
26.67 (c)	Appendix A Subpart B 2.9 (c) and 26.27 (a) (2)
26.69 (a)	NEW
26.69 (b) (1)	26.27 (b) (4)
26.69 (b) (2)	NEW
26.69 (b) (3)	26.27 (b) (4)
26.69 (b) (4)	NEW
26.69 (b) (5)	NEW
26.69 (b) (6)	26.27 (b) (4)
26.69 (b) (7)	26.27 (b) (4)
26.69 (c) (1)	26.27 (a) (3)
26.69 (c) (2)	NEW
26.69 (c) (3)	26.27 (a) (3)
26.69 (c) (4)	NEW
26.69 (c) (5)	NEW
26.69 (d)	NEW
26.69 (e)	NEW
26.69 (f)	26.27 (a) (2)
26.71	NEW
26.75 (a) (1st sentence)	NEW
26.75 (a) (2nd sentence)	26.27 (b) (1st sentence)
26.75 (b)	NEW
26.75 (c)	26.27 (b) (3)
26.75 (d)	26.27 (c)
26.75 (e)	26.27 (b) (2)
26.75 (f)	26.27 (b) (5)
26.75 (g)	26.27 (b) (4)
26.75 (h)	26.24)d) (2)
26.77 (a)	NEW
26.77 (b) (1)	26.27 (b) (1)
26.77 (b) (2)	NEW
26.77 (b) (3)	NEW
26.77 (c)	26.27 (d)
26.81	NEW
26.83 (a)	NEW
26.83 (b)	26.24 (b)
26.85 (a)	Appendix A Subpart B 2.2 (d)
26.85 (b)	NEW
26.85 (c)	Appendix A Subpart B 2.2 (d) (2) (last sentence)
26.87 (a)	Appendix A Subpart B 2.4 (a)
26.87 (b)	Appendix A Subpart B 2.4 (f) (1st sentence)
26.87 (c)	Appendix A Subpart B 2.7 (m)
26.87 (d)	Appendix A Subpart B 2.4 (c)
26.87 (d) (1)	Appendix A Subpart B 2.4 (e)
26.87 (d) (2)	Appendix A Subpart B 2.4 (c) (2nd sentence)
26.87 (d) (3)	Appendix A Subpart B 2.4 (c)
26.87 (e)	Appendix A Subpart B 2.4 (g) (1)
26.87 (f) (1)	Appendix A Subpart B 2.4 (c)
26.87 (f) (2)	Appendix A Subpart B 2.4 (c)

New Section	Based on
26.87 (f) (3)	Appendix A Subpart B 2.4 (c)
26.87 (f) (4)	NEW
26.87 (f) (5)	Appendix A Subpart B 2.4 (c) (2)
26.89	NEW
26.91	NEW
26.93	Appendix A Subpart B 2.4 and new material
26.95	NEW
26.97	NEW
26.99	Appendix A Subpart B 2.4 and new material
26.101	Appendix A Subpart B 2.4 and new material
26.103	NEW
26.105	Appendix A Subpart B 2.4 and new material
26.107	Appendix A Subpart B 2.4 and new material
26.109	NEW
26.111	NEW
26.113	Appendix A Subpart B 2.4 and new material
26.115	Appendix A Subpart B 2.4 and new material
26.117	Appendix A Subpart B 2.4 and new material
26.119	Appendix A Subpart B 2.4 and new material
26.121	NEW
26.123	NEW
26.133	Appendix A Subpart B 2.7 (e) (1)
26.125 (a)	Appendix A Subpart B 2.6 (a)
26.125 (b)	Appendix A Subpart B 2.6 (b)
26.125 (c)	Appendix A Subpart B 2.6 (c)
26.127 (a)	Appendix A Subpart B 2.2 1st paragraph
26.127 (b)	Appendix A Subpart B 2.2 (a) and 2.4 (d)
26.127 (b)	Appendix A Subpart B 2.4 (d)
26.127 (c)	Appendix A Subpart B 2.7 (o) (1)
26.127 (d)	Appendix A Subpart B 2.2 (d)
26.127 (e)	Appendix A Subpart B 2.7 (o) (3) (iii)
26.129 (a)	Appendix A Subpart B 2.4 (c) and 2.7 (a) (1)
26.129 (b)	Appendix A Subpart B 2.2 (b)
26.129 (c)	Appendix A Subpart B 2.7 (b) (2)
26.129 (d)	Appendix A Subpart B 2.7 (a) (2)
26.129 (e)	Appendix A Subpart B 2.7 (d) 1st sentence
26.129 (f)	Appendix A Subpart B 2.7 (c)
26.129 (g)	Appendix A Subpart B 2.4 (i)
26.129 (h)	NEW
26.131	Appendix A Subpart B 2.4 (e)
26.133	Appendix A Subpart B 2.7
26.135	Appendix A Subpart B 2.7 (j)
26.137	Appendix A Subpart B 2.8 (a)
26.137 (e) (4-5)	Appendix A Subpart B 2.8 (b)
26.137 (e) (6-8)	Appendix A Subpart B 2.8 (c)
26.137 (f)	Appendix A Subpart B 2.8 (e) (6)
26.137 (g)	Appendix A Subpart B 2.7 (o)
26.137 (h)	Appendix A Subpart B 2.7 (o)
26.139 (a)	Appendix A Subpart B 2.7 (g) (2)
26.139 (b)	26.24 (d) (1)

New Section	Based on
26.139 (c)	Appendix A Subpart B 2.7 (o) (5)
26.139 (d)	Appendix A Subpart B 2.7 (g) (6)
26.139 (e)	Appendix A Subpart B 2.7 (g) (7)
26.139 (f)	NEW
26.151	NEW
26.153 (a)	26.24(f) and Appendix A Subpart D 4.1
26.153 (b)	Appendix A Subpart B 2.7(l)(2)
26.153 (c)	Appendix A Subpart B 2.7(k)
26.153 (d)	Appendix A Subpart A 1.1 (2)
26.153 (f) (5)	Appendix A Subpart B 2.3 (1)
26.153 (f) 1st paragraph	Appendix A Subpart B 2.3 1st paragraph
26.155	Appendix A Subpart B 2.5
26.157 (a)	Appendix A Subpart B 2.2 1st paragraph
26.157 (b)	Appendix A Subpart B 2.2 (a) and 2.4 (d)
26.157 (c)	Appendix A Subpart B 2.7 (o) (1)
26.157 (d)	Appendix A Subpart B 2.2 (d)
26.157 (e)	Appendix A Subpart B 2.7 (o) (3) (iii)
26.159 (a)	Appendix A Subpart B 2.4 (c) and 2.7 (a) (1)
26.159 (b)	Appendix A Subpart B 2.2 (b)
26.159 (c)	Appendix A Subpart B 2.7 (b) (2)
26.159 (d)	Appendix A Subpart B 2.7 (a)(2)
26.159 (e)	Appendix A Subpart B 2.7 (a)(2)
26.159 (f)	Appendix A Subpart B 2.4 (i)
26.159 (g)	NEW
26.161	NEW
26.163	Appendix A Subpart B 2.7 (e) (1) (substantially revised)
26.165	Appendix A Subpart B 2.7 (j) (substantially revised)
26.167 (a) through (g)	Appendix A Subpart B 2.8 (substantially revised)
26.167 (h)	Appendix A Subpart B 2.7 (o) (3) (i)
26.167 (i)	Appendix A Subpart B 2.8(d)
26.169	Appendix A Subpart B 2.7(g) (substantially revised)
26.181	NEW
26.183 (a)	26.3 and Appendix A Subpart A 1.2 and Appendix. A Subpart B 2.9 (b)
26.183 (b)	NEW
26.183 (b) 1st sentence	Appendix A Subpart B 2.9 (b) 1st sentence
26.183 (c)	26.3 and Appendix.A Subparts A 1.2,B 2.4 (J),B 2.9 (a), and b 2.9 (b)
26.183 (d)	NEW
26.185 (a)	Appendix A Subpart B 2.9 (a)
26.185 (b)	Appendix A Subpart B 2.9 (a) last sentence
26.185 (c)	Appendix A Subpart B 2.9 (c)
26.185 (d)	NEW (more detailed than Appendix A Subpart B 2.9 (c)
26.185 (e)	NEW
26.185 (f)	NEW
26.185 (g)	NEW
26.185 (h)	NEW
26.185 (i)	NEW
26.185 (j) (1)	Appendix A Subpart B 2.9 (d)
26.185 (j) (2)	Appendix A Subpart B 2.9 (d)

New Section	Based on
26.185 (j) (3)	NEW
26.185 (j) (4)	NEW
26.185 (j) (5)	NEW
26.185 (j) (6)	NEW
26.185 (k)	Appendix A Subpart B 2.9 (f)
26.185 (l)	Appendix A Subpart B 2.9 (e)
26.185 (m)	Appendix A Subpart B 2.9 (g)
26.185 (n)	NEW
26.185 (o)	NEW
26.185 (p)	26.24 (e)
26.187	NEW
26.189	NEW
26.195	NEW
26.197	NEW
26.199	NEW
26.201	NEW
26.211 (a)	NEW
26.211 (b)	NEW
26.213 (a) (1)	26.71 (a)
26.213 (a) (2)	26.71 (b)
26.213 (a) (3)	NEW
26.213 (a) (4)	NEW
26.213 (b) (1)	26.21 (b), 26.22 (c), and 26.80 (c)
26.213 (b) (2)	26.21 (b), 26.22 (c), and 26.80 (c)
26.213 (c)	26.71 (c)
26.213 (d)	26.2
26.213 (e)	26.23 (a)
26.213 (f)	NEW
26.213 (g)	NEW
26.215 (a)	Appendix A Subpart B 2.7 (n)
26.215 (b)	NEW
26.217 (a)	26.71 (d)
26.217 (b)	26.71 (d)
26.217 (c)	26.71 (d)
26.217 (d)	26.71 (d)
26.217 (e)	26.71 (d)
26.217 (f)	26.71 (d)
26.217 (g)	NEW
26.219 (a)	NEW
26.219 (b) (1)	26.73 (a) (1)
26.219 (b) (2) (i)	26.73 (a) (2) (i)
26.219 (b) (2) (ii)	26.73 (a) (2) (ii)+(iv) combined
26.219 (b) (2) (iii)	26.73 (a) (2) (iii)
26.219 (b) (3)	NEW
26.219 (b) (4)	NEW
26.219 (c) (1)	Appendix A Subpart B 2.8 (e) (4)
26.219 (c) (2)	Appendix A Subpart B 2.8 (e) (5)
26.219 (c) (3)	NEW
26.219 (d)	NEW

TABLE 2.—DISTRIBUTION TABLE FOR PART 26

Current section	*Replaced by:*
26.1 (from beginning to “programs”)	26.1
26.1 (following “programs”)	Deleted
26.2 (a) (first clause)	26.2 (a) (to “and”)
26.2 (a) (balance of 1st sentence)	26.2 (b) (from “to” to end)
26.2 (a) (2nd sentence)	26.21 (1st sentence)
26.2 (a) (3rd sentence to end)	26.25 (a) (1)(2) and (3)
26.2 (b) (1st sentence)	26.25 (a)
26.2 (b) (2nd sentence to end)	26.3 (f)
26.2 (c) (1st sentence)	26.3 (e)
26.2(c) (from “shall implement” to end)	26.3 (f)
26.2 (d)	26.3 (c)
26.3	26.5
26.4	26.7
26.6	26.9
26.8	26.13
26.10 (a) (from beginning through “manner”)	26.23 (a)
26.10 (a) (balance of 1st sentence)	26.23 (b)
26.10 (b)	26.23 (c)
26.10 (c)	26.23 (d)
26.20 (introductory paragraph, 1st sentence)	26.27 (a)
26.20 (introductory paragraph, 2nd sentence)	26.213 (d)
26.20 (introductory paragraph, final sentence)	26.27 (b) (sentence before “(1)”)
26.20 (a)	26.27 (b)
26.20 (b)	26.27 (b) (7)
26.20 (c)	26.27 (c)(1)
26.20 (d)	26.27 (c)(2)
26.20 (e)	26.27 (c)(3)
26.20 (f)	26.27 (d)
26.21 (a)	26.29 (a)
26.21 (b)	26.29 (c)
26.21 (b) (last sentence)	26.213 (b)(1)
26.22	Deleted
26.23 (a)	26.3(d) and 26.21
26.23 (b)	26.21
26.24 (a) (first sentence to “(1)”)	26.31 (a)
26.24 (a) (balance of paragraph)	26.31 (c) (substantially revised)
26.24(b)	Subparts E, F, and G
26.24 (c)	26.31 (d)
26.24 (d)	Subparts E, F, and G
26.24 (e)	Subpart H
26.24 (f)	26.31 (d)(3) and requirements in Subpart G

Current section	*Replaced by:*
26.24 (g)	26.31 (d)(4) and Subparts E, F, and G
26.25	26.35
26.27 (a)	Subpart C
26.27 (b)	Subpart D
26.27 (c)	Subpart D
26.27 (d)	26.77(c)
26.28	26.39
26.29	26.37
26.70	26.221
26.71	26.211, 26.213, and 26.215
26.73	26.219 (substantially revised)
26.80	26.41 (substantially revised)
26.90	26.223
26.91	26.225
Appendix A Subpart A, 1.1 (1)	26.3
Appendix A Subpart A, 1.1 (2)	26.31(d) (substantially revised)
Appendix A Subpart A, 1.1 (3)	Subparts F and G
Appendix A Subpart A, 1.2	26.5
Appendix A Subpart B, 2.1(a)	26.31(d)(1)
Appendix A Subpart B, 2.1 (b)	26.31(d)(1)
Appendix A Subpart B.2.1 (c)	Subparts E, F, and G
Appendix A Subpart B.2.1 (d)	26.31(d)(6)
Appendix A Subpart B.2.1 (e)	26.31
Appendix A Subpart B.2.2 (Initial paragraph)	Subparts F and G
Appendix A Subpart B.2.2 (a), (b), and (c)	26.115, 26.117, 26.129, 26.159, 26.169
Appendix A Subpart B.2.2 (d)(1), (2), and (3)	26.85
Appendix A Subpart B.2.2 (d) (4)	Deleted
Appendix A Subpart B.2.3	26.31(b), and requirements in Subparts E, F, and G
Appendix A Subpart B.2.4 (a)	26.87 (a)
Appendix A Subpart B.2.4 (b)	26.85
Appendix A Subpart B.2.4 (c)	26.87 (d) and (f)
Appendix A Subpart B 2.4 (d)	26.117
Appendix A Subpart B 2.4 (e)	26.87 (d) (1)
Appendix A Subpart B 2.4 (f) 1st sentence	26.87 (b)
Appendix A Subpart B 2.4 (f)(1) through (f)(4)	26.95 through 26.115 and Subparts Fand G
Appendix A Subpart B 2.4 (g) (1) through (g)(24)	Subparts E, F, and G
Appendix A Subpart B 2.4 (h) (1st sentence)	26.87(f)(5)
Appendix A Subpart B 2.4 (h) (balance of section)	26.113, 26.117, and 26.135
Appendix A Subpart B 2.4 (i)	26.117

Current section	*Replaced by:*
Appendix A Subpart B 2.4 (j) (first two sentences)	26.115 and 26.185
Appendix A Subpart B 2.4 (j) (final sentence)	Deleted
Appendix A Subpart B 2.5(a)	26.155(a)
Appendix A Subpart B 2.5(b)	26.153
Appendix A Subpart B 2.5(c)	26.155(c)
Appendix A Subpart B 2.5(d)	26.155(d)
Appendix A Subpart B 2.5(e)	26.155(e)
Appendix A Subpart B 2.5(f).	26.155(f)
Appendix A Subpart B 2.6(a)	26.125(a)
Appendix A Subpart B 2.6(b)	26.125(b)
Appendix A Subpart B 2.6(c)	26.125(c)
Appendix A Subpart B 2.7(a)	26.127, 26.129, 26.157, and 26.159
Appendix A Subpart B 2.7)b)	26.129(b) and 26.159(b)
Appendix A Subpart B 2.7(c)	26.129(f) and 26.159(h)
Appendix A Subpart B 2.7(d)	26.157 and 26.159
Appendix A Subpart B 2.7(e)	Validity screening and initial validity test requirements in 26.131and 26.161 and initial cutoff levels in 26.133 and 26.163(a)
Appendix A Subpart B 2.7(f)	26.163(b)
Appendix A Subpart B 2.7(g)(1) through (5)	26.169
Appendix A Subpart B 2.7(g)(6) and (7)	Requirement for annual summary in 26.169(k)
Appendix A Subpart B 2.7(g)(8)	26.215
Appendix A Subpart B 2.7(h)	26.159(i) and by 26.135(c)
Appendix A Subpart B 2.7(i)	Subparts F and G
Appendix A Subpart B 2.7(j)	26.113, 26.135, 26.165
Appendix A Subpart B 2.7(k)	26.153(c)
Appendix A Subpart B 2.7(l)	26.153((f)(1) and 26.153(b)
Appendix A Subpart B 2.7(m)	26.87(c) and 26.221
Appendix A Subpart B 2.7(n)	26.215(a)
Appendix A Subpart B 2.7(o)(1)	26.127(c) and 26.157(c)
Appendix A Subpart B 2.7(o)(2), (o)(3), and (o)(4)	26.137 and 26.167
Appendix A Subpart B 2.7(o)(5)	26.139(c) and 26.153(f)(2)
Appendix A Subpart B 2.8 (a)	26.137(a) and 26.167(a)
Appendix A Subpart B 2.8 (b)	26.137
Appendix A Subpart B 2.8 (c)	26.167
Appendix A Subpart B 2.8 (d)	26.137 and 26.167
Appendix A Subpart B 2.8 (e)(1) to (e)(3)	26.137
Appendix A Subpart B 2.8 (e)(4), (e)(5), and (e)(6)	26.137 and 26.219
Appendix A Subpart B 2.9 (a) and (b) (through “contract employee”)	26.183
Appendix A Subpart B 2.9 (b) (balance of section), (c), (d), (e), (f), and (g)	26.185
Appendix A Subpart C 3.1	26.37(e) and 26.153(f)(3)

Current section	*Replaced by:*
Appendix A Subpart C 3.2	26.75(i)(4), 26.165(f)
Appendix A Subpart D 4.1	26.153