[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 26

RIN 3150 - AF12

Fitness For Duty Programs

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations for Fitness for Duty (FFD) programs to update these requirements and enhance consistency with advances in other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other Federal drug and alcohol testing programs that impose similar requirements on the private sector. The amendments 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 final rule ensures 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 final rule also grants, 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 partially grants a petition for rulemaking (PRM-26-2) submitted by Barry Quigley on December 28, 1999.

DATES: This final rule is effective 30 days from today's date. However, licensees and other applicable entities may defer implementation of this rule, except for Subparts I and K, until 365 days from today's date. Subpart I must be implemented by licensees and other applicable entities no later than 18 months after today's date. Licensees and other applicable entities shall comply with the requirements of Subpart K as of 30 days after today's date.

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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 an 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 research literature, as well as initiatives by industry, the Substance Abuse and Mental Health Services Administration of the Department of HHS (SAMHSA, formerly the National Institute on Drug Abuse), 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 rule 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. 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 work-hour guidelines. Those guidelines were:

(1) An individual should not be permitted to work more than 16 consecutive hours (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 7-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 in some cases. 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.

On September 28, 1999, the Commission received a petition for rulemaking (PRM-26-2) from Barry Quigley. (The petition is discussed in greater detail in Section II.B of this document) 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, under 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 request (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). Under 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 of worker fatigue.

During the development of the 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. Subsequent to 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 periods of extended work hours, matters unique to security personnel and stakeholder input obtained through public meetings concerning the worker fatigue rulemaking and the order. The NRC imposed the requirements in the order 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 10 CFR Part 26, Subpart I, Managing Fatigue, for security force personnel replace the requirements imposed by the order. Differences between the requirements in Subpart I and the requirements imposed by the order, and the rationale for those differences, are discussed in Section IV.D of this document.

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 former 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 issue one or both proposed 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 final rule withdraws the proposed rule published on May 9, 1996.

D. Public Input Accepted Since 2000 “Affirmed Rule”

In preparing this rule, the NRC considered comments received by OMB on the prior Part 26 final rule affirmed by the Commission in an SRM dated December 4, 2000.
The NRC also considered feedback received from industry, as well as other interested parties and members of the public. The NRC held 11 stakeholder meetings on the drug and alcohol

testing portions of the rule during 2001–2004, and 13 stakeholder meetings on the fatigue portions of the rule during 2002–2003. Following the Commission's decision to combine the two rulemaking efforts, the NRC held one stakeholder meeting on the combined rule in July, 2004, and two 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*on February 15, 2002 (67 FR 7093). The NRC received feedback 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 after 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 final rule in a manner to ensure it is clearly understandable, will be consistently interpreted, and does not result in unintended consequences. Many of the stakeholders' comments directly resulted in changes. When a comment was included in a provision, the comment is discussed in Section VI of this document.

Many comments were received during the years the meetings were held. The draft proposed rule language was changed and re-posted to the web numerous times.

Following the publication of the August 25, 2005 (70 FR 50442) proposed rule, the NRC proposed a 4-month period to accept public comment submissions. However, the NRC accepted comments for several months after the proposed deadline for the submission of public comments. These comments are discussed in Section V of this document.

The NRC also held several public meetings after the proposed rule was published to increase stakeholder involvement in the rulemaking. These meetings were held on September 21, 2005 (ADAMS Accession No. ML052420363), November 7 and 9, 2005 (ADAMS Accession No. ML052990048), December 15, 2005 (ADAMS Accession No. ML053400002), and March 29-30, 2006 (ADAMS Accession No. ML060650535).

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 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 former 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.

Section 26.41(b) of the final rule partially grants two aspects of the petition. The required audit frequency for licensees and other entities who are subject to 10 CFR Part 26 has been reduced from the nominal 1-year frequency in the former 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 will be conducted as part of the 2-year audits of the licensee or other entity's FFD program, under § 26.41(b).

Section 26.41(c)(1) of the final rule partially denies two aspects of the petition. The nominal annual audit requirement for HHS-certified laboratories has been retained. In addition, the annual audit requirement has been 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 the audit requirements in the 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 detail 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 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 evaluated the merits of PRM-26-2, the comments received in response to the PRM, and assessed the Policy on Worker Fatigue. The NRC 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 concluded 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. Therefore, the final rule grants, PRM-26-2, in part. 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 will similarly revise this inspection procedure following issuance of the final rule. The self-disclosure of sleeping disorders by licensed operators (item 4) is being addressed by the NRC as a separate effort from this 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 former rule required 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 off site 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 final rule maintains the former requirement for random drug and alcohol testing for all 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
ITAAC	Inspections, Tests, Analyses, and Acceptance Criteria
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 Final Action

A. Overview

A review of FFD program experience confirms that the former regulatory approach of 10 CFR Part 26 was fundamentally sound and provided a means of deterrence and detection of substance abuse at licensee facilities. FFD Program Performance Reports through 2005 are published on the NRC's website, http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html.

Nonetheless, the NRC believes that revisions were needed to improve the effectiveness and efficiency of FFD programs; enhance consistency with advances in similar rules and guidelines, including HHS' Mandatory Guidelines for Federal Workplace Drug Testing Programs (herein called 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. Goals of the Rulemaking Activity

The NRC is amending 10 CFR Part 26, Fitness For Duty Programs. The 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 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 of 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; and

(7) Protect the privacy and other rights (including due process) 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 final rule relate to each goal. The major changes for each subpart and the reasons for those changes are described in Section IV.C of this document. For each of the many specific changes, 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 changes to the former rule that will 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 HHS Guidelines and other Federal drug and alcohol testing programs (e.g., those required by the DOT that impose similar requirements on the private sector. Goal 1 is central to this rulemaking activity. Many changes are included in the final 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 HHS Guidelines, upon which the former rule was based.

The President of the United States designated HHS as the agency responsible for the Federal workplace drug testing program. HHS' 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 the most recent HHS 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 have been 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 specimen validity tests to determine whether a urine specimen has been adulterated, diluted, or substituted. This final rule adopts 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 former 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 change to 10 CFR Part 26 that is included from the proposed HHS Guidelines is permission for licensees to use validity screening tests 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 validity screening tests 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 including 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 changes to 10 CFR Part 26 that incorporate the recent revisions to the HHS Guidelines, the 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. This final rule also reflects 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. Subpart I, Managing Fatigue, adds clear and enforceable requirements for licensee management of worker fatigue to 10 CFR Part 26. The requirements 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 of this document discusses the specific reasons for each worker fatigue provision. Section I.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 making 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 reduction in the period within which pre-access testing must be performed from 60 days, in former § 26.24(a)(1), to 30 days or less, in Subpart C [Granting and Maintaining Authorization]. This change improves the effectiveness of the pre-access test in detecting drug and alcohol use by individuals who are applying for authorization to have the types of access or perform the duties that require them to be subject to Part 26. Reducing the number of breath specimens required for alcohol testing from two each for initial and confirmatory testing, in former Section 2.4(g)(18) in Appendix A to Part 26, to one specimen for the initial test and one for the confirmatory test also increases the efficiency of FFD programs without compromising the accuracy and validity of alcohol test results.

Another example of rule changes related to Goal 3 is establishing a regulatory framework for the management of worker fatigue that appropriately balances the need for flexibility to manage plant exigencies 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 the access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. Part 26 and the access authorization requirements each contain provisions that require establishing the trustworthiness and reliability of personnel before granting unescorted access to the protected areas of nuclear power plants. The NRC

determined that, because both sets of requirements share this same goal, revising Part 26 was necessary to 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 former Part 26 addressed 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 enhancements to existing access authorization programs. Therefore, it was necessary to revise the related provisions in Part 26.

Goal 5 – Improve 10 CFR Part 26 by eliminating or modifying unnecessary requirements. The final rule incorporates a number of changes to eliminate or modify unnecessary requirements. The experience NRC has gained over the years since Part 26 was promulgated has enhanced the agency's understanding of implementation issues experienced by the industry, and the NRC is now eliminating or modifying some provisions, while at the same time maintaining protection of public health and safety and the common defense and security.

For example, because of inconsistencies in how licensees interpreted the 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. The revisions to Part 26 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 final rule is organized to facilitate implementation, as compared to the former rule, which has generated many questions from licensees. Therefore, in the final 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 apply to licensees' FFD processes. In addition, the NRC has made many language changes to improve clarity. This substantial reorganization, which substantially reduces the likelihood of variations in FFD programs across the industry through differing interpretations of the rule, improves the protection of public health and safety and the common defense and security. The final 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 the final 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 Part 26 have eliminated the need for a guidance document for provisions pertaining to drug and alcohol testing. 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. Therefore, industry desired the rule to be more specific and detailed, in lieu of a guidance document.

Goal 7 – Protect the privacy rights and other rights (including due process) of individuals who are subject to 10 CFR Part 26. This goal was an implicit objective of the former rule, and the final rule continues to protect the privacy and other rights of individuals (including due process) 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 the DOT and HHS to modify many of their requirements for such testing to more clearly protect privacy and other rights of individuals. Many of the 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 is making 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 the final rule prohibits any testing of "Bottle B, the second portion of a split urine specimen, or retesting an aliquot of a specimen" without the donor's permission.

C. Overview of Final Rule

The final rule is divided into subparts that contain related requirements. Each subpart is assigned a descriptive title to aid users in locating rule provisions and to simplify cross-referencing within the final rule. By grouping related requirements and presenting them generally in the order in which they apply to licensees' and other entities' FFD processes, the final rule improves the ease of implementing the rule. For example, the final rule adds Subpart K [FFD Programs for Construction] to consolidate FFD requirements for new reactor construction. Also, the provisions that were contained in Subparts J [Recordkeeping and Reporting Requirements] and K [Inspections, Violations, and Penalties] of the proposed rule are now contained in Subparts N and O, respectively, of the final rule.

The major topics addressed in each subpart and the reasons that the NRC made

major changes to the former rule are described below. A detailed cross-reference table between the former and final Part 26 provisions is included at the end of this notice.

Subpart A Administrative Provisions

The first subpart, Subpart A, replaces the General Provisions portion of the former rule, but continues to address the same subject matter. Thus, Subpart A addresses the purpose and scope of the rule, provides definitions of important terms used in the final rule, and updates former provisions related to requests for specific exemptions, interpretations of the rule, and communications with the NRC. The final rule also adds a section to Subpart A that consolidates FFD program applicability requirements for categories of individuals.

Subpart B Program Elements

Subpart B of the final rule reorganizes and amends former §§ 26.10 through 26.29. These sections of the former rule specified the performance objectives that FFD programs were required to meet and the FFD program elements that licensees and other entities were required to implement to meet the performance objectives. However, the final rule does not include former § 26.27 [Management actions and sanctions to be imposed] in Subpart B for two reasons. First, the final rule is reorganized to be consistent with the order in which licensees and other entities implement their programs. Because Subpart B is 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 rule. Second, the subject matter of former § 26.27 is sufficiently important and complex that a separate subpart is warranted. Therefore, the final rule presents requirements related to management actions and sanctions in Subpart D [Management Actions and Sanctions to be Imposed].

Subpart C Granting and Maintaining Authorization

Subpart C of the final rule substantially amends former 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 final rule introduces 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 avoid substance abuse, and, therefore, may be permitted to have the types of access or perform the duties described in § 26.4 [FFD program applicability to categories of individuals], as a result of the process described in this subpart. For example, in the case of nuclear power plant personnel, a licensee may permit an individual who is "authorized" under Part 26 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 unescorted access to an individual or permit an individual to maintain unescorted access to protected areas. 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, perform a credit and criminal history check, and interview individuals who have knowledge of the applicant for authorization. However, historically there have been some inconsistencies and redundancies between the Part 26 requirements related to granting and maintaining unescorted access 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 imposed an unnecessary burden on licensees in other cases. Therefore, a central goal of adding Subpart C to the final 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 unescorted access under Part 26 and also under other, related requirements, including, but not limited to, the January 7, 2003 access authorization orders issued by the NRC to nuclear power plant licensees.

The requirements in Subpart C are based on several fundamental changes to the NRC's approach to the authorization requirements in former 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 reasonable 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 VI of this document with respect to § 26.23(a) in terms of the increased insider threat since the terrorist attacks of September 11, 2001. One change to former Part 26 authorization requirements that reflects this concern is the elimination of temporary access authorization requirements in the second sentence of former § 26.27(a)(4). Other changes are discussed in Section VI with respect to the specific provisions that incorporate them.

A second, related change to the NRC's approach to authorization requirements, which has informed Subpart C, is an increased concern with the sharing of information about individuals between licensees and other entities. At the time the former 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 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 on 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 former FFD regulations were written on the basis that individual licensees would maintain independent, site-specific FFD programs and shared limited information, and that the majority of nuclear personnel would remain at one site for years, the former regulations did 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, Subpart C requires licensees and other entities to collect

and share greater amounts of information than under the former rule, subject to the protections of individuals' privacy that are specified in § 26.37 [Protection of information]. As a result, individuals who are subject to the rule will establish a detailed "track record" within the industry that will 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 contributes to providing reasonable assurance that individuals who are granted and maintain authorization under Part 26 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 have unescorted access to protected areas, 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. There is also 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 required under Subpart C has the potential to result in a greater number of these individuals being banned from working in the industry. Therefore, the NRC has added several requirements to Subpart C to minimize these consequences for individuals who are able

to demonstrate that they are effectively coping with a substance abuse problem. Additional requirements for protecting information to be gathered about individuals under Part 26 are specified in § 26.37 [Protection of information]. The detailed changes to former requirements are discussed in Section VI with respect to the specific provisions that incorporate these requirements.

In general, the authorization requirements in Subpart C are 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 final rule requires 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 final rule requires licensees and other entities to complete before granting authorization to the individual is reduced. The need for original information gathering in these instances is reduced because licensees and other entities will have access to all of the information that previous FFD programs have collected about the individual under the final rule,.

For individuals who have established a favorable track record in the industry, the steps that licensees and other entities are required to complete in order to grant authorization to an individual also depends 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 final rule requires 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 final rule requires licensees and other entities to complete fewer steps in order to grant authorization to the individual. There are several reasons that the final rule requires 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 are 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 has developed an active substance abuse problem or undergone other 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, it is less likely that the individual could have undergone significant changes in lifestyle or character that

would be undetected.

Therefore, the final rule establishes categories of requirements for granting authorization to an individual that 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. Section 26.55 [Initial authorization] establishes 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. Section 26.57 [Authorization update] establishes 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. Section 26.59 [Authorization reinstatement] establishes authorization requirements for individuals who previously held authorization under Part 26 and whose last period of authorization was terminated favorably within the past year. Section 26.69 [Authorization with potentially disqualifying fitness-for-duty information] defines 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 are 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 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 final rule incorporates these time periods within Part 26.

In general, the steps that are required under this part to grant authorization to an individual who has recently held authorization and whose most recent period of authorization was terminated favorably are 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 NRC has strengthened the requirements for a rigorous evaluation process contained in the former § 26.27(e) that licensees and other entities are required to meet before granting authorization to an individual about whom potentially disqualifying FFD information has been disclosed or discovered (see § 26.69). The final rule requires 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 exceptions to the self-disclosure and employment history, suitable inquiry, and pre-access testing requirements are specified in §§ 26.61 [Self-disclosure and employment history], 26.63 [Suitable inquiry], and 26.65 [Pre-access drug and alcohol testing], respectively. The final rule also requires licensees and other entities to ensure that applicants are subject to random testing, as specified in § 26.67 [Random drug and alcohol testing of individuals who have applied for authorization].

Subpart D Management Actions and Sanctions

Subpart D of the final rule replaces former § 26.27(b) and (c) and divides the former provisions into two separate sections that specify requirements for responding to FFD policy violations in § 26.75 [Sanctions], and indications of impairment in § 26.77 [Management actions regarding possible impairment]. The final rule adds a new § 26.73 [Applicability] to specify the entities and individuals to whom the requirements of the subpart apply. The former rule has been reorganized to generally reflect the order in which the requirements apply to licensees' and other entities' FFD processes, and to group related requirements into separate sections.

Therefore, the NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

In general, Subpart D includes three significant changes from the related provisions in the former rule that are each intended to provide a stronger deterrent to engaging in the unwanted actions specified in the subpart. First, the final rule increases 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 are necessary in order to strengthen the effectiveness of the rule in providing reasonable 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 have the types of access or perform the duties listed in § 26.4 [FFD program applicability to categories of individuals].

Second, the final rule requires 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. However, some licensees have imposed lesser sanctions for alcohol violations, an approach that is inconsistent with the NRC's intent. Therefore, the final rule rectifies this situation by explicitly requiring the same minimum sanctions for abuse of alcohol as formerly required for the use of illegal drugs.

Third, the final rule adds the sanction of permanent denial of authorization for any individuals who subvert or attempt to subvert the testing process. The former rule permitted 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 imposed different sanctions and some individuals were granted authorization or permitted to maintain

authorization when they 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 final rule establishes a minimum sanction that all FFD programs must impose to deter attempts to subvert the testing process, as well as provide reasonable 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 have been made to meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs. The NRC has made other changes to former § 26.27(b) and (c) in Subpart D primarily to eliminate or modify unnecessary requirements and clarify the intent of former provisions.

Subpart E Collecting Specimens for Testing

Subpart E of the final rule reorganizes and amends the requirements related to collecting specimens for drug and alcohol testing that were contained in former § 26.24 [Chemical and alcohol testing] and interspersed throughout former Appendix A to Part 26. The subpart groups the related requirements and presents them in the order in which they would be implemented by FFD programs. The final rule also eliminates some redundancies in the provisions of the former rule that were related to specimen collections. The NRC has made these changes to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

In general, the procedures in this subpart are more detailed than those in Appendix A to the former rule and NRC regulations that are based on a risk-informed, performance-based approach, for several reasons. First, the more detailed procedures in Subpart E will increase the consistency of Part 26 drug and alcohol specimen collection procedures with those of other

Federal agencies and therefore, take advantage of the scientific and technical advances that have been made in workplace drug and alcohol testing programs since the former Part 26 was promulgated, as discussed in Section IV.B of this document. Second, the final rule permits FFD programs to accept and rely upon other FFD programs that are implemented under this part, as well as the programs of other Federal and State agencies, to a much greater extent than is permitted under the former rule. The permission to rely on other programs improves the effectiveness and efficiency of FFD programs (Goal 3 of the rulemaking) and improves the rule by eliminating or modifying unnecessary requirements (Goal 5 of the rulemaking). For example, under § 26.69(b)(6), the final rule permits licensees and other entities to rely on 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 3-year period following the violation, and is transferring from one licensee's site to another.

The final rule requires the receiving licensee or entity to continue the followup testing program. However, the final rule permits 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 final rule permits this reliance on other programs, more detailed requirements for conducting the activities on 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, the final rule incorporates a greater level of detail in the specimen collection procedures of the final rule for the reasons discussed in Section IV.B.

The NRC has made other major changes to the former rule's requirements for collecting specimens for drug and alcohol testing to incorporate specimen validity testing requirements from the HHS Guidelines into Part 26 (Goal 1 of this rulemaking) and modify former 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 of the final rule presents detailed requirements for conducting initial urine specimen validity and drug tests at licensee testing facilities, as permitted in § 26.24(d)(1) of the former rule and § 26.31(d)(3)(ii) of the final rule. The subpart is entitled, "Licensee Testing Facilities," for brevity, but permits other entities who are subject to the rule to establish and operate drug testing facilities under the final rule.

The NRC has added this subpart to the final rule to group together in a single subpart the rule's requirements that are related to licensee testing facilities, which were intermixed with requirements related to drug testing at HHS-certified laboratories in Appendix A to Part 26 in the former rule. The final rule presents the requirements that are applicable to licensee testing facilities and HHS-certified laboratories in two separate subparts because the provisions of the former rule were not always clear with respect to which requirements applied to which type of testing facility. Also, the final rule includes the requirements that apply to both types of facilities in both subparts so that it is unnecessary for licensees and other entities who do not operate licensee testing facilities to be concerned with any provisions in Subpart F. Although many of the requirements in this subpart are redundant with similar requirements in Subpart G [Laboratories Certified by HHS], these changes meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The most important change in Subpart F to the former requirements for licensee testing facilities is the addition of new requirements for licensee testing facilities to conduct initial 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 initial urine specimen validity testing are discussed with respect to § 26.31(d)(3)(ii). 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, the rule permits licensees and other entities 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 are not 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, Subpart F permits licensee testing facilities to use commercially available 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 § 26.5 [Definitions], the final rule uses the term “validity screening test” to refer to these commercially available tests. The term “initial validity test” refers to instrumented validity testing.

At the same time that the HHS published its regulations to require specimen validity

testing, which have been incorporated in the final 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 Subpart F also incorporates. 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 presents 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 group together the former requirements in Appendix A to Part 26 as they relate to HHS-certified laboratories. However, the final rule updates the former requirements 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 former rule's requirements for HHS-certified laboratories are the incorporation of extensive requirements for urine specimen validity testing.

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

Subpart H in the final rule reorganizes, clarifies, and enhances former 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 Subpart C [Granting and Maintaining Authorization] and also with respect to imposing sanctions and taking actions to prevent an individual from performing duties that require an individual to be subject to this part under Subpart D [Management Actions and Sanctions]. The former requirements, which were interspersed throughout the rule, are grouped together in Subpart H to make them easier to locate within the final rule, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. The subpart also makes several significant changes to the former requirements.

In general, Subpart H includes more detailed requirements for determining FFD policy violations and conducting determinations of fitness than were included in the former rule. The NRC has added these more detailed requirements 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 final rule permits licensees and other entities to rely on the determinations made by other Part 26 programs to a greater extent than the former rule. For example, § 26.63(b) of the final rule permits 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, from previous periods of authorization. The reasons for adding these permissions were discussed previously in this section, with respect to Subpart C [Granting and Maintaining Authorization]. However, 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 former requirements and establish clear minimum standards for those processes. Therefore, the subpart includes greater detail to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Under the final rule, licensees and other entities 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 final rule extends this requirement to the review of positive confirmatory validity test results, consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed in Section VI with respect to § 26.31(d)(3)(i). An MRO review of adulterated or substituted validity test results from an HHS-certified laboratory 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 adulterated or substituted 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. The NRC added a requirement for the MRO to review adulterated or substituted validity test results to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 and ensure that the individuals are afforded accurate and consistent testing. The HHS Guidelines also require the MRO to review adulterated and substituted validity test results. Therefore, adding this requirement to the final rule also meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Another significant change that the final rule makes to former requirements is the establishment of a new position within FFD programs — the “substance abuse expert” (SAE). The SAE is 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 NRC has added the SAE position 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 positive, adulterated, substituted, or invalid 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 final rule permits MROs to serve as SAEs if they meet the qualifications for this role that are established in this subpart. But, the rule requires licensees and other entities to rely on other healthcare professionals who have the necessary qualifications to conduct determinations of fitness if the MRO does not meet the SAE qualification requirements.

Second, the NRC believes that healthcare professionals other than licensed physicians may have the requisite knowledge and skills to serve as SAEs under the rule. Therefore, the final rule defines the position of SAE in terms of the knowledge and skills required, and permits healthcare professionals other than licensed physicians to serve in this role.

Third, under the final rule, FFD programs are 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 plays in assuring the common defense and security and public health and safety when making a determination of fitness on 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.

The NRC has adapted many of the provisions in the subpart 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 former Part 26.

Subpart I Managing Fatigue

Subpart I of the final rule strengthens 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 [Reserved]

As a result of adding Subpart K [FFD Programs for Construction] to the final rule, several subparts of the proposed rule have been renumbered. The provisions contained in Subpart J of the proposed rule have been moved to Subpart N of the final rule.

Subpart K FFD Programs for Construction

As a result of reorganizating the final rule, the NRC has moved the provisions contained in Subpart K of the proposed rule [Inspections, Violations, and Penalties] to Subpart O of the final rule.

The final rule adds a new Subpart K to revise and increase the level of detail of FFD requirements contained in § 26.3(e) of the proposed rule pertaining to FFD programs for new reactor construction. The NRC has added this subpart to the final rule to clarify the requirements applicable to entities conducting construction activities in response to public comments that raised concerns with the proposed requirements. A detailed description of these public comments, as well as a summary of the features and objectives of Subpart K can be found in Section V of this document. A detailed section-by-section analysis of the provisions of Subpart K can be found in Section VI of this document.

Subpart L [Reserved]

Subpart M [Reserved]

Subpart N Recordkeeping and Reporting Requirements

As a result of reorganizing the proposed rule, the NRC has moved the provisions contained in Subpart J of the proposed rule [Recordkeeping and Reporting Requirements] to this subpart of the final rule. The NRC has added Subpart N to the final rule to reorganize the former rule's requirements for maintaining records and submitting reports to the NRC. The subpart combines and amends two sections of the former rule: Section 26.71 [Recordkeeping requirements] and § 26.73 [Reporting requirements], and incorporates the record retention requirements of former §§ 26.21(b), 26.22(c), and 26.80(c). The final rule adds a new § 26.209 [Applicability]. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule, by grouping related requirements together in the subpart.

Major changes to the former rule's requirements for recordkeeping and reporting reflect the addition of requirements for specimen validity testing to the final rule, the addition of requirements for managing worker fatigue at nuclear power plants, and 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 O Inspections, Violations, and Penalties

As a result of reorganizing the proposed rule, the NRC has moved the provisions contained in Subpart K of the proposed rule [Inspections, Violations, and Penalties] to this subpart of the final rule. The NRC added Subpart O to the final rule to combine into one subpart former §§ 26.70 [Inspections], 26.90 [Violations], and 26.91 [Criminal penalties]. The NRC has grouped these sections together in one subpart because they each establish requirements related to the NRC's oversight of the implementation of FFD programs. Section 26.821 [Inspections] retains the requirements in former § 26.70. Section 26.823 [Violations] retains the

requirements in former § 26.90 [Violations]. Section 26.825 [Criminal penalties] retains the requirements in former § 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 at nuclear power plants. Subpart I, Managing Fatigue, of the final rule includes these requirements and establishes an integrated approach to fatigue management for nuclear power plant workers, with fatigue prevention, detection, and mitigation as the fundamental components. The requirements in Subpart I provide a substantial increase in the protection of public health and safety and common defense and security. In establishing the provisions of this final 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 former regulatory framework; the excessive hours formerly worked by many nuclear power workers; and the practices of other industries and countries for regulating work hours. In addition, the NRC held many public meetings with the nuclear industry and the public to discuss provisions for the final rule.

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 workers' tolerance of these conditions also influence worker fitness for duty. As a consequence, fatigue is a complex phenomenon that requires an integrated approach to manage effectively. The requirements in Subpart I were developed on the premise

that fatigue management requires the collaboration of individual workers and licensees.

Each of the requirements in Subpart I is discussed in detail in Section VI. However, because Subpart I presents an integrated fatigue management approach, this section discusses the principal findings that led to the NRC's 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 final 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 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 former regulatory framework did 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 extended work weeks and the overuse of work-hour limit deviations;

(5) The former regulatory framework included requirements that were inadequate and incomplete for effective fatigue management;

(6) Ensuring effective management of worker fatigue through rulemaking substantially enhances 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. These 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 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., Final 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 controls, such as standardized work practices and independent verification, 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 rapid, accurate decisions, and communicate and work as a team. The following effects of fatigue on cognitive abilities are the primary focus of the 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 central to safe nuclear power plant operations. Fatigue is associated with more risky strategies and decreases in the effort

individuals exert in decision-making (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 causing degraded performance, recent research has helped characterize the magnitude of these effects relative to a historical

FFD concern: impairment from alcohol intoxication. Part 26 prohibited the use of alcohol on site and within several hours before a tour of duty, and established 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 provisions of 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 breath alcohol cutoff level below 0.05 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 are 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., Final Rule; 65 FR 25544 May 2, 2000). The effects of extended working hours on worker performance can be exacerbated when many extended shifts are scheduled in succession. The National Institute

for Occupational safety and Health published a report in 2004 (Caruso et.al., 2004) that reviewed 52 recent reports examining the association between long work hours and illness, injuries, health behaviors, and performance. NIOSH reported that “a pattern of deteriorating performance on psychophysiolgical tests as well as injuries while working long hours was observed across study findings, particularly when 12-hour shifts combined with more than 40 hours of work a week.”

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 the preamble to the proposed rule, 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 indicated that deviations from the limit of 72 hours in 7 days continue to account for more than 80 percent of the deviations authorized. During the public 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 Commissioned by the NRC 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 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. Such start times typically cause workers to wake before 6 a.m., thereby reducing the amount of sleep that can be obtained between midnight and 6 a.m., the most effective time period for most people to sleep. 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 are specific to U.S. nuclear power plant workers, in the general U.S. population, these 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). These changes are beyond the individual's control. In addition, several studies have suggested caution with regard to the abilities of individuals to self-monitor their capacity 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, 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 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 asserts 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 former regulatory framework did not include consistent or readily enforceable requirements to address worker fatigue.

The principal components of the former regulatory framework for matters pertaining to working hours and fatigue for non-security personnel were (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 limited 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 former regulatory framework applicable to worker fatigue, including licensee technical specifications 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 final rule, and the principal findings include:

(a) <u>NRC's Policy on Worker Fatigue</u> – NRC guidance documents do not prescribe requirements. Guidance documents establish policy or provide advice on meeting a regulatory requirement. As a result, a policy is enforceable only to the extent that the guidelines have been incorporated into a license condition or technical specifications. 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, 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 had 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 has been 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 has resulted in inconsistent interpretation and implementation of technical specifications 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 work-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 capabilities.

– 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 have been 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 has not been implemented consistently from one nuclear power plant to another. Work hours included within the limits at some nuclear power plants have not been 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 former § 26.10 required 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 former 10 CFR Part 26 contained specific requirements pertaining to alcohol and drug usage, it did not include prescriptive requirements regarding fatigue. Rather, former § 26.20 used 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 has been 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, have made it difficult for the NRC to enforce worker fatigue requirements and work-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 requirements 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 included 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 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.

NEI conducted a survey in the summer of 2000 concerning industry control of work hours for personnel subject to the technical specifications (letter dated August 29, 2000, from J. W. Davis, NEI, to G. M. 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 per year increased from 7 percent in 1997 to 11 percent in 1999. The percentage of licensed operators working in excess of 600 hours of overtime per year

increased from 13 percent in 1997 to more than 16 percent in 1999. The NRC considers these percentages to 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 in this sample are reported in detail in Appendix 3 of the 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 has been excessive, and has been inconsistent with the intent of the NRC's Policy on Worker Fatigue.

In addition to excessive work hours and work-hour guidelines 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 final rule establishes requirements to address this need.

(5) The former regulatory framework included requirements that were 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 specifications were inadequate to provide 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 has been revised to a 10-hour break. The basis for this revision to increase the length of this break period is described in detail in Section VI with respect to § 26.205(d)(2)(i).

In addition, although the policy established an objective of a nominal 40-hour work week, the specific work hour guidelines of the policy and most technical specifications for the administrative control of work hours have principally focused on acute fatigue. These guidelines did 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, or continuous task demands 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 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 former regulatory framework for addressing cumulative fatigue became particularly apparent in the months following the terrorist attacks of September 11, 2001. 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 were 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, establishes controls to address cumulative fatigue. Limits to mitigate cumulative fatigue for nuclear power plant security personnel were implemented by Order EA-03-038. The final rule codifies, with changes, these requirements. Changes to those limits that have been imposed by this rule are discussed in detail in Section VI, which also includes a detailed discussion of the limits and other controls to mitigate cumulative fatigue for other personnel who perform safety-related duties at nuclear power plants.

(c) The former regulatory framework did not effectively ensure that fatigue from causes

other than work hours was 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 abilities 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). Subpart I, Managing Fatigue, requires a comprehensive fatigue management program. One example is the strengthening of FFD training requirements concerning worker fatigue. The training requirements will improve the effectiveness of behavioral observation and the 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 will 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 were ensured under the former regulatory framework, including Order EA-03-038 (for security personnel), the NRC's Policy on Worker Fatigue, and licensee technical specifications. Licensee FFD programs included 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 former 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) ensured adequate protection of public health and safety and the common defense and security. However, there were substantial limitations to the former regulatory framework, as detailed in this section. Therefore, although the previous regulatory framework provided adequate protection, including work-hour controls in 10 CFR Part 26 provides a substantial increase in public health and safety and the common defense and security. The NRC has incorporated worker fatigue provisions in 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 limits on work hours for nuclear plant workers in eight other countries, as well as six other industries in the United States and Canada. These are summarized in Attachment 1 of SECY-01-0113. Although many factors influence specific regulatory limits, and requirements for other industries should be considered in context, the NRC found that the NRC's former 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 that apply to multiple industries. 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). Not satisfied 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) limit driving time to 11 cumulative hours following 10 consecutive hours off duty; (3) prohibit work after the end of the fourteenth hour after the driver began work; and (4) require long break recovery periods to prevent cumulative fatigue (68 FR 22456-22517; April 28, 2003, as amended by 70 FR 50071; August 25, 2005).

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 earlier in 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 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. 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 final rule differs from other Federal agencies' requirements with respect to specific work hour requirements and requires 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 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 final 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 former regulatory framework, the excessive hours formerly worked by many nuclear power plant 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 final rule. The specific basis for each provision of the fatigue management portions of the final rule are discussed in Section VI.

The 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 will 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 Comments Submitted on Proposed Rule

Description of Public Comments and Public Meetings

The NRC received 81 written public comments on the proposed Part 26 published on August 26, 2005. The NRC also considered six comments submitted on a previous working draft of the proposed rule that NRC posted on its website on May 19, 2005, but which were received too late to consider at that time. These 87 written comments contained more than 350 pages of material. The stakeholders who submitted these 87 comments are as follows: 25 (29 percent) from nuclear energy industry representatives, including several substantive comments from NEI; five (6 percent) from other organizations; seven (8 percent) from unions; 21 (24 percent) from individuals who work in the nuclear energy industry (i.e. operators, maintenance workers); 15 (17 percent) from other individuals; and 14 (16 percent) from anonymous

commenters.

The NRC considered comments contained in the transcript of a public meeting held on September 21, 2005, in which 28 individuals, including NRC staff, spoke. Four written comments were submitted anonymously at this meeting. The NRC also considered comments from several other public meetings: November 7 and 9, 2005 (ADAMS Accession No. ML052990048) to provide clarification on the proposed rule; and December 15, 2005 (ADAMS Accession No. ML053400002) regarding NEI's proposed alternative approach to the work-hour portions of the proposed rule.

The written comments received on the proposed rule addressed many issues that were of stakeholder concern. The NRC analyzed all of these comments as part of the process for developing this final rule. A complete analysis of the comments may be found in "Summary and Analysis of Public Comments Received on Proposed Revisions to 10 CFR Part 26 – Fitness for Duty Programs," dated December 13, 2006.

In particular, commenters raised several important concerns relating to fatigue management, the application of FFD requirements to entities involved in new plant construction and manufacturing activities, and validity testing of urine specimens. These concerns are discussed in some detail below. As discussed in Section VI, commenters also raised numerous other smaller issues that led the NRC to modify many final rule provisions. Finally, many comments resulted in minor changes to the proposed rule to improve clarity in the rule's organization and language, consistent with Goal 6 of this rulemaking. Virtually all of the comments supported the objectives of the proposed rule.

Public Comment on Subpart I

The NRC has reorganized the overall structure of the proposed rule and renumbered several subparts. This necessitated renumbering the affected sections of Subpart I [Managing Fatigue].

Subpart I contains requirements for the management of worker fatigue at nuclear power plants. Most comments recommended modifications to Subpart I to address specific concerns with the proposed rule language or certain provisions of the rule. However, the vast majority of the stakeholders commenting on Subpart I expressed their general support for the NRC's objective of establishing a set of clear and enforceable requirements to address the management of worker fatigue at nuclear power plants. Commenters supported the fatigue provisions for various reasons. In particular, commenters expected that the rule would provide increased clarity of work hour requirements, reduction of forced overtime, reasonable assurance that the risk of fatigue-related events is managed, increased staffing levels, and prevention of worker injuries. Those who opposed the rule asserted that it would place an unnecessary burden on licensees, reduce worker income, and make it more difficult for licensees to attract supplemental workers during outages.

The NRC received several substantive comments that addressed specific provisions in proposed § 26.199 [Work hour controls]. This section would have established requirements for the control of work hours for a limited scope of personnel at a nuclear power plant. In general, the individuals who would have been subject to these requirements perform functions that most directly affect the protection of public health and safety and common defense and security. The provisions that were the subject of these comments were proposed § 26.199(d)(2)(ii), which would have required a minimum 24-hour break in any 7-day period; proposed § 26.199(d)(2)(iii), which would have required a minimum 48-hour break in any 14-day period; and proposed § 26.199(f) [Collective work hour limits], which would have required licensees to control the average work hours of specified duty groups (e.g., operations, security). The NRC also received substantive comments on the reporting requirements in Subpart I of the proposed rule. Specifically, the comments concerned the proposed § 26.197(e) [Reporting] which would have required licensees to provide information concerning the implementation of certain work

hour requirements as part of an annual FFD program report.

Proposed requirements for a minimum 24-hour break in any 7-day period

Section 26.199(d)(2)(ii) of the proposed rule would have required a minimum 24-hour break in any 7-day period. Commenters noted that licensees who currently use 8-hour schedules often include periods of 7 consecutive work days in their schedules. These schedules limit the frequency of shift rotations and enable licensees to conduct training on a Monday-through-Friday schedule. The commenters also asserted that the requirement for a minimum 24-hour break in any 7-day period would substantially reduce licensee flexibility in scheduling 8-hour shifts and would cause them to switch to 12-hour shifts. The NRC agrees that the proposed requirement for a minimum 24-hour break in any 7-day period would have adversely affected licensee scheduling of 8-hour shifts s described in the comments and has revised the maximum number of work days that the rule permits between breaks as follows –

Section 26.205(d)(2)(ii) of the final rule replaces proposed § 26.199(d)(2)(ii) and requires a minimum 34-hour break in any 9-day period. In revising the requirement, the NRC considered that, although the final rule permits more consecutive work shifts for 8-hour and 10-hour shift schedules, the additional flexibility allows licensees to more readily optimize their 8-hour shift schedules to minimize the transitions between day, evening, and night shifts that can lead to worker fatigue. Although this relaxation also allows more consecutive shifts for individuals on 10-hour shifts, these individuals typically do not work a rotating schedule and therefore do not experience the disruption of their circadian cycle that exacerbates the cumulative fatigue effects of consecutive work shifts. The rule also establishes minimum day of requirements in § 26.205(d)(3) that effectively limit within each shift cycle the number of times individuals can work the 8 consecutive work days allowed by § 26.205(d)(2)(ii). The scheduling of 12-hour shifts is unaffected by this requirement because § 26.205(d)(1)(iii) effectively limits the scheduling of 12-hour shifts to not more than 6 consecutive days. The final rule also

provides the licensee with sufficient flexibility to accommodate other practical considerations, such as scheduling training on a Monday-through-Friday basis, and allows a contingency day for 8-hour shift schedules that include a series of seven consecutive 8-hour shifts.

The final rule also revises the minimum duration of the break period from 24 hours, as specified in § 26.199(d)(2)(ii) of the proposed rule, to a minimum of 34 hours. The revision more clearly reflects the NRC's intent to require a periodic "day off" in which individuals have the opportunity for two consecutive sleep periods without an intervening work period. The 34-hour break duration provides this opportunity, supports use of forward rotating and fixed shifts, and allows for the possibility that individuals may work 26 hours in a 48-hour period contiguous to the break.

Proposed requirement for a minimum 48-hour break in any 14-day period and collective work hour limits

Section 26.199(d)(2)(iii) of the proposed rule would have required a minimum 48-hour break in any 14-day period. This requirement would have provided periodic breaks to prevent and mitigate cumulative fatigue. Although this requirement would have also been applicable when a reactor was operating, the NRC considered it particularly important for the control of work hours during outages. During these periods, successive weeks of extended work hours (i.e., up to 72 hours per week) are common. However, the NRC received substantive comments regarding this provision.

Several commenters expressed concern that a mandatory 48-hour break would limit the ability of licensees to provide adequate coverage for unplanned maintenance (e.g., to quickly restore inoperable equipment). Several commenters also stated that the break requirements would encourage supplemental workers to seek jobs in other industries that offer more overtime. Therefore, commenters were concerned that this unintended consequence of the break requirements would harm the licensees' ability to attract and retain qualified workers.

Other commenters stated that, although the recovery concept is scientifically supported, the approach used to prevent cumulative fatigue should consider existing work schedules and scheduling practices. Commenters also asserted that a 48-hour break during a series of night shifts would adversely affect the circadian cycle of those workers who had adjusted to the night shift. These commenters stated that for workers on the night shift, having 1 day off provides an additional rest period and allows the worker to maintain a consistent pattern of work and sleep habits, thus reducing the risk of accidents on the job. However, two days off may interfere with a worker's sleep cycle, requiring the individual to readjust to the night shift after a 2-day break. Commenters also asserted that a 1-day break in any 7-day period is more than adequate when combined with other rule provisions to address cumulative fatigue.

The NRC considered public comments on the proposed 48-hour break requirement in conjunction with public comments on the collective work hour limits of the proposed rule. The collective work hour limits in proposed § 26.199(f) would have required licensees to control the average work hours of specified groups of personnel that perform the same job function. In general, this provision would have required licensees to ensure that the collective work hours of individuals within each group did not average more than 48 hours per week, when averaged over a period of up to 13 weeks. The objective of the collective work hour limits, like the 48-hour break requirement, was to prevent cumulative fatigue. In contrast to the 48-hour break requirement, the collective work hour limits would typically have been applicable only when a reactor was operating. Thus, the 48-hour break requirement in conjunction with the 24-hour break requirement of proposed § 26.199(d)(2)(i) would have been the principal mechanism to address cumulative fatigue during outages, and collective work hour limits would have been the principal means of preventing cumulative fatigue while a plant was operating.

Some commenters stated that the collective work hour limits would be an ineffective means for addressing fatigue because it is experienced on an individual basis. That is, the

collective work hour limits could not ensure that each individual would be protected from cumulative fatigue. One commenter stated that the collective work hour controls would allow licensees to force individuals to work overtime. Other commenters stated that licensees may be able to manipulate the collective work hour calculations. Still other commenters asserted that the collective work hour controls were unnecessary to mitigate the effects of cumulative fatigue and that they would limit licensee flexibility to increase work hours for a job-duty group based on operational needs. These commenters stated that other rule provisions, such as the work scheduling requirement, individual work hour limits, individual break requirements, and the provisions concerning fatigue assessments and the self-declaration process, adequately address the possibility of cumulative fatigue.

The NRC agrees, in part, with certain comments on the proposed 48-hour break requirement and the collective work hour limits of the proposed rule, and has revised the final rule accordingly. To address cumulative fatigue during periods when a plant is operating, the NRC replaced the proposed rule requirement for a minimum 48-hour break in § 26.199(d)(2)(iii) and the collective work hour limits in § 26.199(f) with the requirements in § 26.205(d)(3) of the final rule. This section requires that each individual subject to the work hour requirements has a minimum average number of days off per week while the plant is operating. This provision addresses comments on the proposed 48-hour break requirement and collective work hour limits as follows:

- The minimum day-off requirements of § 26.205(d)(3) address cumulative fatigue on an individual basis. In contrast to the proposed collective work hour limits, the final rule provides more uniform assurance of worker FFD and addresses the concern that, although duty groups could have met the collective work hour requirements, individuals in those groups may have worked excessive hours.
- The minimum day-off requirements of § 26.205(d)(3) establish limits that are tailored to

the duration of the shifts that individuals work (e.g., individuals on 8-hour shifts must average at least 1 day off per week; individuals on 10-hour shifts must average 2 days off per week). As a consequence, in contrast to the single set of break requirements in the proposed rule, the final rule provides a better correlation between the number of hours an individual works and the amount of restorative rest required by the rule.

- The minimum day-off requirements of § 26.205(d)(3) establish a flexible approach to addressing cumulative fatigue. This provision requires a minimum average number of days off per week, averaged over a shift cycle of up to 6 weeks. Accordingly, the rule does not require that individuals meet the average each week, but does ensure that individuals receive a minimum number of days off over the course of the shift cycle. As a consequence, the NRC has established a requirement that accommodates a wide range of scheduling practices and short-term fluctuations in workload. The requirement also allows licensees considerable flexibility in accommodating individual worker preferences concerning the timing and distribution of days off.
- The minimum day-off requirements of § 26.205(d)(3) establish limits that are practical and likely to impose less administrative burden on licensees than would have been required by the collective work hour limits in the proposed rule[1]. By establishing limits that require the control of work hours on an individual basis, licensees need not define and track membership in duty groups. In addition, the requirements in the final rule largely adopt an approach proposed by NEI as an industry-recommended alternative to the group work hour controls. Thus, the NRC expects that licensees will consider the administrative requirements of this work hour control method to be less burdensome.

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[1]Although the NRC believes that the minimum day off requirements of § 26.205(d)(3) will impose less administrative burden on licensees than the collective work hour limits of the proposed rule, the NRC has conservatively retained the administrative burden estimate of the collective work hour limits for § 26.205(d)(3) of the final rule.

To address cumulative fatigue during periods when a plant is in a unit or planned security system outage, the NRC has replaced the proposed rule requirements for a minimum 48-hour break (§ 26.199(d)(2)(iii)) and the collective work hour limits applicable to security personnel during outages (§ 26.199(f)(2)(i)) with the requirements in § 26.205(d)(4) and (d)(5) of the final rule. These sections require individuals subject to the work hour requirements of the rule to have a minimum number of days off in each successive (i.e., non-rolling) 15-day period of the outage. Section 26.205(d)(4) applies to individuals who perform the operations, maintenance, health physics or chemistry, and fire brigade duties described in § 26.4(a)(1) through (a)(4) of the final rule and requires a minimum of 3 days off in each successive 15-day period of a unit outage. Section 26.205(d)(5) applies to individuals who perform the security duties described in § 26.4(a)(5) of the final rule and requires a minimum of 4 days off in each successive 15-day period of a unit outage or planned security system outage. These final rule provisions address those comments on the 48-hour break and collective work hour requirements applicable to outage periods as follows:

- The minimum day-off requirements of § 26.205(d)(4) do not mandate that licensees schedule 2 consecutive days off as would have been required by the 48-hour break requirement. As a result, licensees are better able to establish schedules that minimize the potential for disrupting the circadian cycle of individuals who are on fixed night shifts.
- The minimum day-off requirements of § 26.205(d)(4) allow licensees substantial flexibility in scheduling the required days off within the 15-day outage periods. As a result, licensees are able to implement a range of scheduling options to meet known outage schedule demands and have the flexibility to revise schedules as necessary to address emergent needs.
- The minimum day-off requirements of § 26.205(d)(4) allow licensees to use a predictable, repeating schedule. The requirement permits a schedule of four

consecutive 12-hour shifts followed by 1 day off. This 5-day sequence can repeat three times in each 15-day period creating a schedule that is predictable and repeatable, characteristics typically desired by workers and schedulers. This requirement also limits the number of consecutive work shifts to prevent cumulative fatigue and includes sufficient periodic days off to mitigate fatigue.

- The minimum day-off requirements of § 26.205(d)(4), in conjunction with the other requirements in § 26.205 [Work hours], allow a maximum workweek of 72 hours and an average workweek of 67.2 hours for a period of up to 60 days. As a result, the requirement allows licensees to offer substantial amounts of overtime within these limits to attract supplemental workers for outage activities, while ensuring that schedules remain consistent with the management of worker fatigue. The NRC acknowledges that some individuals may want to work more than 72 hours, or even more than 84 hours, per week. However, the NRC notes that the work hour limits of § 26.205 apply only to those duties that the agency believes have the most direct impact on the protection of public health and safety and common defense and security. As a result, the requirements do not prevent individuals from working more than 72 hours per week, unless those individuals are performing (1) duties on structures, systems, and components (SSCs) that a risk-informed evaluation process has shown to be significant to public health and safety, (2) critical emergency or fire response duties, or (3) duties as members of the site security force that are necessary for the execution of the site security plan.
- Several commenters recommended that the 8-week exclusion period be extended to 10 weeks to accommodate extended outages for activities such as reactor vessel head and steam generator replacements. In conjunction with these comments, industry stakeholders asserted at public meetings held for this rulemaking that cumulative fatigue

was not a concern during these extended outages because individuals often had periods when they were not required to work the extended work hours typically associated with outages. In response to this comment, the NRC included a provision in § 26.205(d)(6) of the final rule which allows licensees to extend the 60-day exception for individuals by 1 week for each 7-day period the individual worked not more than 48 hours during the outage. Thus, the rule allows the outage exception to be extended when directly justified by an individual's actual work history. In light of the significant work hours allowed by the requirements, as discussed in the preceding paragraph, the NRC considers this approach to be better justified for the management of worker fatigue than the proposal for a blanket extension of the outage exclusion to 10 weeks.

Section 26.205(d)(5) of the final rule applies to individuals who perform the security duties described in § 26.4(a)(5) and requires a minimum of 4 days off in each successive 15-day period of a unit outage or planned security system outage. This minimum days-off requirement is comparable to the work hour limits imposed for security personnel by order EA-03-038 and the 60-hour collective work hour average that the proposed rule would have required. The NRC replaced the collective work hour limits for security personnel with the requirements in § 26.205(d)(5) of the final rule for the following three reasons:

(1) In addition to other commenters, security personnel expressed concerns about the effectiveness of the collective work hour controls to fully protect against impairment from fatigue for all personnel in a group..

(2) Elimination of the 48-hour break requirement sets aside a key requirement for preventing an excessive number of consecutive work days that would have otherwise been allowed under the collective work hour limits. As a result, the NRC concluded that the collective work hour limits, absent the 48-hour break requirement, would not provide reasonable assurance that nuclear power plant security personnel would be protected from cumulative

fatigue from excessive work hours.

(3) Revision of the outage requirements to a minimum of 4 days off in a 15-day period avoids the potential confusion and additional burden of two different approaches and accounting systems (i.e., minimum day off requirements and collective work hour limits) for the control of personnel work hours at a site.

The NRC believes that the minimum day-off requirements of § 26.205(d)(3) through (d)(6) of the final rule address the range of comments on the rule, several of which expressed opposing views regarding the need to relax the requirements or to make them more restrictive.

The NRC does not agree with the comments that asserted that the proposed requirements to address cumulative fatigue were unnecessary and that a 1-day break in any 7-day period is more than adequate when combined with the other rule provisions (e.g., self-declaration and training) to address cumulative fatigue. The NRC believes that requirements are necessary to ensure that individuals are not impaired by the cumulative fatigue that would result if individuals routinely worked the maximum work hours (e.g., 72 hours per week) that would otherwise be allowed by the requirements in § 26.205(d)(1) and (d)(2).

The NRC acknowledges the important role of self-declaration and training in fatigue management, as noted by some commenters, but also recognizes the inherent limitations of these provisions to effectively address fatigue, particularly during periods of outage schedule conditions. As noted by Michael T. Coyle, NEI, comment letter #49, and supported by several other commenters, “for many supplemental workers the availability of overtime is a key factor in where they decide to work.” The NRC also recognizes that outages are periods when individuals may perceive increased schedule pressure and is aware that at least one site bonuses are offered for perfect attendance during outages. Self-declaration would likely cause individuals to forfeit a portion of that overtime and possibly a bonus. As a result, despite the best efforts of licensees to emphasize safety and worker FFD, the NRC anticipates that self-

declaration and training in methods to obtain adequate rest may not be implemented as effectively or consistently during outage periods as during periods of routine plant operation, and therefore, they are not a substitute for work hour controls that effectively prevent cumulative fatigue.

In asserting that a 1-day break is more than adequate to address cumulative fatigue, industry stakeholders have cited the basis for the Federal Motor Carrier Safety Administration's (FMCSA) minimum 34-hour break provision for commercial motor vehicle (CMV) operators. The NRC reviewed the FMCSA regulations (49 CFR 395), associated statements of consideration (65 FR 25544, 2000; 70 FR 49978, 2005), the findings of an expert panel commissioned by the FMCSA (Belenky et.al., 1998), and a petition for review of the final rule (No. 06-1078, U.S. Court of Appeals for the District of Columbia). The NRC concluded that, for a limited range of conditions, the studies cited by FMCSA support a 34-hour break as an appropriate minimum rest period. However, the NRC staff does not agree that the basis cited by the FMCSA supports a requirement that would routinely allow 72 hours of work before such a break is required. The NRC notes that:

(1) The FMCSA regulations for CMV operators include requirements that prohibit driving after 60 hours of duty in 7 days. By contrast the NEI proposal would allow 72 hours of work in a 7-day period, excluding turnover.

(2) The statement of considerations for the FMCSA regulation establishes that long work weeks with minimum break periods are the exception for CMV operators. The FMCSA sets forth this information as a premise for the adequacy of the 34-hour break. By contrast, application of the industry proposed requirement to the control of work hours during unit outages would allow licensed operators[2] and other plant personnel to work regularly occurring

[2]At multi-unit sites with common control rooms, all licensed operators would be subject to the limits applicable to unit outages, including operators responsible for operating units.

periods of multiple consecutive 72-hour work weeks with minimum break periods. The NRC notes that Public Citizen, the International Brotherhood of Teamsters, and several other parties have submitted a petition for review of the FMCSA requirements, and that a central argument of the petition is that the FMCSA did not justify that the 34-hour break would offset the cumulative fatigue of duty hours in excess of the weekly limits.

(3) Contrary to the NEI assertion that a 34-hour break is "more than adequate" the expert panel commissioned by the FMCSA described the 34-hour break as "absolutely minimal." Further, the expert panel noted that a fundamental assumption for the adequacy of the 34-hour break is that it will provide two consecutive nights of uninterrupted sleep between midnight and 6 a.m. Given common outage scheduling practices, the NRC believes that no workers on night shifts and few workers on day shifts would meet this assumption and that industry's assertion that one day off will provide full recovery from six consecutive 12-hour shifts is not justified.

In addition, the NRC does not agree with industry stakeholder comments an opportunity for 8 hours of sleep between shifts prevents cumulative fatigue. This argument is contrary to common experience in that it implies workers should be able to work 12 hours per day, without degradation in their performance, for an unlimited number of days. To the contrary, the National Institute for Occupational Safety and Health (NIOSH), found that "up to five consecutive 12/14-hour shifts *** creates the potential for excessive fatigue, even when 8 hours of sleep per day are obtained" (2000 NIOSH 3). Similarly, the NRC notes that it has received increased reports of excessive fatigue following extended periods of 12-hour shifts, such as in the months following the terrorist attacks of September 11, 2001, and during the extended head replacement outage at Davis Besse (NRC Inspection Report 05000346/2004003, dated March 31, 2004, ADAMS Accession No. ML040910335). The NRC found that workers typically did not average more than 60 work hours per week during these

periods. As a result, even if a 34-hour break was adequate to mitigate cumulative fatigue from 72 or more hours of work, the 1 day off in a 7-day period that the industry's proposed would not ensure that breaks would be provided on a sufficient frequency to prevent weekly occurrences of cumulative fatigue. A NIOSH review (Caruso,et al., 2004) of 52 recent reports examining the association between long work hours and illness, injuries, health behaviors, and performance reported "a pattern of deteriorating performance on psychophysiolgical tests as well as injuries while working long hours was observed across study findings, particularly when 12-hour shifts combined with more than 40 hours of work a week."

Considering the limitations of the technical basis cited by the industry and its applicability to outage scheduling practices and operating experience and technical literature indicating that 1 day off in 7 days is not adequate for recovery when individuals are working in excess of 60 hour per week, the NRC concluded that the industry proposal would not effectively prevent cumulative fatigue for multiple consecutive weeks of extended work hours. The NRC considers the minimum day off requirements of the final rule to provide adequate flexibility to accommodate emergent work and a range of scheduling practices while supporting reasonable assurance of worker FFD. By limiting the use of the maximum work hours and minimum break guidelines to a "temporary basis," the requirements of § 26.205(d)(3) through (d)(6) are consistent with the NRC's long-standing "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors." Furthermore, the NRC considers these requirements necessary to prevent licensees from routinely scheduling extended periods of 72-hour work weeks given that licensees commenting on the proposed rule asserted that workweeks of 72 hours for up to 10 weeks are acceptable for maintaining human performance and that these work hours are necessary to attract supplemental workers.

Proposed reporting requirements

Many comments addressed the reporting requirements for the fatigue provisions. Section 26.197(e) of the proposed rule would have required licensees to submit, as part of the annual FFD program report required under § 26.717 [Fitness-for-duty program performance data] of the final rule, information concerning the licensee's implementation of the work hour controls and management of worker fatigue. The proposed rule would have required the annual report to include a summary of the waivers the licensee approved during the calendar year, information pertaining to instances of job duty groups exceeding a collective work hour average of 48 hours in any averaging period during the calendar year, and information pertaining to instances of fatigue assessments conducted during the calendar year.

Several commenters from industry asserted that the reporting requirements in the proposed § 26.197(e) should be deleted from the rule because they would not provide new or unique information to the NRC, are unnecessary to protect public health and safety, are unnecessary to facilitate NRC oversight of the revised rule, and are unduly burdensome. One commenter further stated that the NRC's proposed FFD rule and supporting materials did not demonstrate that the industry would fail to comply with the requirements of the revised rule without the imposition of these reporting requirements. The commenter asserted that the existing regulatory process is adequate to ensure compliance with the rule. Some commenters believed that the reporting requirement would create a significant duplication in licensee efforts, noting that proposed § 26.199(j) required periodic reviews by licensees to assess the effectiveness of the work hour controls, and that these reviews are documented and trended under the licensee's corrective action program which is periodically inspected by the NRC.

Some commenters stated that the reports the rule would require will not be a meaningful indicator of licensee performance in managing work hours because a number of valid conditions may warrant waivers of work hour controls. Two commenters suggested that the rule require licensees to report the number of workers covered under § 26.199(a) [Individuals

subject to work hour controls] of the proposed rule to provide appropriate context for the annual reporting of waivers.

Several commenters from industry also stated that the NRC has not met its obligation under the Paperwork Reduction Act with respect to the information collection requirements proposed in § 26.197(e). They argued that the NRC failed to adequately justify the need for these provisions to achieve the objectives of the proposed FFD rule and failed to objectively support its estimate of the burden placed on affected licensees. The commenters asserted that the annual report would require at least 30 clerical hours to develop and 20 management hours to review.

In response to public comments on the reporting requirements, the NRC revised certain requirements for the inclusion of fatigue management information in the annual FFD program report. The NRC also made conforming changes to the reporting requirements as part of changes to other provisions of the rule.

Section 26.203(e) [Reporting] of the final rule presents the reporting requirements associated with licensee implementation of Subpart I. This section does not retain the requirements in proposed § 26.197(e)(2) for the reporting of information pertaining to the control of collective work hours because the final rule does not include this provision. In addition, the agency revised the requirements in proposed § 26.197(e)(1) and (e)(2) in response to comments that the required information would not provide a meaningful indication of licensee performance in managing work hours because a number of valid conditions may warrant waivers of work hour controls. Through its review of authorized waivers from the work hour limits in plant technical specifications, the NRC has found that waivers are most frequently associated with outage activities. Accordingly, the NRC has revised the final rule to require licensees to report whether a waiver of the work hour requirements in § 26.205 was associated with an outage activity. The NRC has similarly revised the requirement for reporting information

pertaining to fatigue assessments. The final rule requires licensees to report whether an individual assessed for fatigue was engaged in an outage-related activity at the time of the event or condition that resulted in the need for such an assessment.

As a result of these revisions, the NRC will be better able to interpret a licensee's changes in waiver use over time and understand why certain annual reports for a given licensee may indicate a heightened level of waiver use relative to the licensee's previous reports. The NRC recognizes that outages are not the only cause of waivers; however, the agency expects that most other causes of waiver use will be for substantially shorter periods of time or involve smaller groups of workers and that these other conditions would not have a substantive effect on overall waiver use. For unique causes that may have more substantive effects (e.g., licensee response to hurricanes), the NRC is likely to be aware of or able to identify these conditions if they were to significantly affect waiver use. Furthermore, the NRC intends to consider waiver use in conjunction with the reported fatigue assessment information. Therefore, the agency will be able to determine whether waiver use may be associated with the incidence of fatigue assessments conducted for cause, following events, or in response to self-declarations by individuals asserting that they are not able to safely and competently perform their duties because of fatigue. The NRC notes that the frequency of waiver use (i.e., how often individuals exceed the work hour limits while performing functions important to safety and security) indicates the potential for worker fatigue to affect the performance of these functions, regardless of whether a waiver is the result of an activity associated with an outage or a cause that is beyond the licensee's control.

In addition to requiring an indication of whether a waiver was associated with an outage activity, the NRC revised the annual report requirement to require a frequency distribution of waivers for each of the five duty groups described in § 26.4(a) of the final rule. As a result, the annual report would include, for example, a table that shows the number of operators who

received just one waiver during the year, the number of operators who received two waivers during the year, and so on. The NRC incorporated this requirement in the final rule in response to comments that the rule should also require licensees to report the number of workers covered under § 26.199(a) of the proposed rule to provide an appropriate context for the annual reporting of waivers. The NRC understood that the intent of this comment was to provide a basis for evaluating the number of waivers from the work hour controls relative to the number of individuals subject to those controls. The NRC chose not to require licensees to report the number of individuals covered under § 26.4(a) of the final rule because that number will vary throughout the course of the reporting period, particularly when the reporting period includes a unit outage. In addition, the NRC believes that the required distribution of waivers more effectively provides context to the waiver use information by indicating whether the waivers were concentrated among individuals performing a certain duty and whether the waiver use in a duty group was associated with relatively few individuals or distributed among many individuals.

The NRC does not agree with comments that the requirements for including fatigue management information should be deleted from the rule because they will not provide new or unique information to the NRC, are unnecessary to protect public health and safety, are unnecessary to facilitate NRC oversight of the revised rule, and are unduly burdensome. In choosing to retain reporting requirements for waiver use, the NRC considered several aspects of the work hour requirements in the final rule. First, the NRC established the work hour limits in the final rule at levels such that the potential for fatigue is substantive for individuals working in excess of those limits. Second, the rule permits licensees to authorize waivers of the limits only for circumstances in which the additional work hours are necessary to prevent or mitigate a condition adverse to safety or security. Finally, the rule only requires a waiver if the individual is operating or maintaining an SSC that a risk-informed evaluation process has shown to be important to the protection of public health and safety or if the individual is performing specified

functions that are essential to an effective response to a fire, plant emergency, or implementation of the site security plan. As a result, information concerning licensee use of waivers indicates (1) the number of hours worked on risk-significant activities by individuals who are at increased potential for impairment, and (2) how often a licensee must mitigate or prevent a condition adverse to safety while relying on individuals who are at increased potential for impairment. The NRC considers this unique information, not otherwise reported, to be relevant to the agency's mission.

The NRC similarly considered the need to retain reporting requirements regarding fatigue assessments and any management actions in response to the fatigue assessments. The final rule requires fatigue assessments:

(1) For cause, following an observation indicating impaired alertness;

(2) Post event, following a plant event or worker injury meeting specified significance criteria,

(3) Following a self-declaration of being unfit for duty; and

(4) When a licensee returns an individual to duty with a break of less than 10 hours after the individual was relieved of duties because of a fatigue assessment conducted for cause or in response to a self-declaration of fatigue.

With regard to fatigue assessments following self-declarations, the NRC notes that individuals are only assessed when a licensee denies a worker's request for relief from duty (i.e., a rest break). In all other instances, the individual will be allowed time off from duty under the licensee's administrative practices and will not require a fatigue assessment. Given these requirements of the final rule, licensee annual reporting of information pertaining to fatigue assessment will indicate how often:

(1) Individuals are relieved of duty because of observed impairment from fatigue;

(2) Fatigue is identified as a causal factor in significant plant events and injuries;

(3) Individuals are required to remain on duty following their declaration that they are not fit for duty because of fatigue; and

(4) Individuals are returned to duty with less than a 10-hour break following a for-cause assessment for fatigue or a self-declaration of fatigue.

The NRC considers this unique information not otherwise reported that is relevant to the agency's mission, particularly when reviewed in conjunction with information concerning the licensee's use of waivers from the work hour limits.

The NRC expects that the information provided by licensees in response to the annual reporting requirements in Subpart I will facilitate NRC oversight of the implementation of the requirements through the following means:

- Consistency, efficiency, and continuity of NRC oversight—Information provided through the annual FFD program performance reports concerning fatigue management will enable the NRC to achieve a higher level of consistency and efficiency in the oversight of the implementation of the requirements in Subpart I and in the enforcement of those requirements. Without the reporting requirements, the NRC's inspection of licensee FFD programs would likely be limited to individual inspectors evaluating licensee fatigue management for a sample of workers at a site for a limited time period. These assessments would necessarily be conducted without the benefit of broader contextual information from the site or the industry normative information that would be available through the annual reports. In contrast, the annual reports will help ensure a common perspective and maintain consistency among inspectors conducting the oversight process. In addition, the annual reports can enhance the efficiency of the NRC inspection process by providing information necessary to allow the agency to focus inspection resources on duty groups (e.g., security or maintenance) or issues (e.g., self-declaration) that may warrant review. The reports will enable the NRC to be better

focused in preparing for the inspection, reduce the burden of onsite inspection hours, and potentially reduce the total number of hours required for a baseline inspection. Further, the annual reporting will also help to achieve a more complete and continuous assessment of licensee performance because the NRC intends to conduct the baseline inspection of FFD programs only once every 2 years.

- Evaluation of rule implementation for lessons learned—Although the NRC and stakeholders have made extensive efforts to ensure clear and enforceable requirements that are effective and practical for the management of worker fatigue, the rule introduces the potential for unintended consequences and lessons learned. In addition, changes in the size and composition of the nuclear industry may have unforeseen implications for site staffing and fatigue management. The NRC expects that the site-specific and normative information obtained through the annual reports can provide important insights regarding opportunities to amend the rule to improve its effectiveness or reduce unnecessary burden. The NRC notes that information provided by the FFD program performance reports was the basis for reducing the random testing rate for drugs and alcohol required in a previous amendment to Part 26.
- Consistent interpretation of waiver criterion—The final rule provides licensees the discretion to use waivers to exceed the work hour limits, thereby allowing levels of work hours that could adversely affect worker FFD. The principal basis for allowing waivers is to reduce the additional staffing burden that licensees would otherwise incur if waivers were not available to address exigent circumstances. The annual reporting of waiver use in conjunction with the reporting of information concerning fatigue assessments will enable the NRC to ensure that licensees use this discretion in a manner consistent with the objectives of the rule and not as a means to compensate for a lack of adequate staffing. Further, although the use of waivers is limited to conditions when the work

hours are “necessary to prevent or mitigate a condition adverse to safety or security,” the NRC recognizes the potential for licensees to develop different interpretations regarding this criterion. Some industry commenters on the proposed rule took exception to the NRC’s characterization of high levels of waiver use at some sites as abuse. These commenters suggested that differences in licensee waiver practices could be attributed to the policy being subject to a number of interpretations during the many years that it has been in effect. Regardless of the cause of the differences in licensee use of work hour control waivers, the NRC considers it prudent to address, through rulemaking, the lessons learned from past implementation of the policy and provide a level of oversight through the annual reporting requirement that will ensure consistent implementation of the waiver criteria in the future.

In addition to the reasons cited in the preceding paragraphs explaining the need for reporting requirements to ensure the effective and efficient oversight of the implementation of the rule, the NRC considers the reporting requirements to be justified and beneficial for the following additional reasons:

- Consistency with other Part 26 requirements and performance objective—The final rule retains the requirement of the former rule that licensees must report the results of drug and alcohol testing and the performance objective for reasonable assurance that individuals are not impaired from any cause (§§ 26.719 [Reporting requirements] and 26.23(b) of the final rule). In addition, several studies discussed in detail in Section IV.D of this document have demonstrated that worker fatigue can produce levels of impairment that are comparable to blood alcohol concentrations above the levels permitted by this rule. Further, given the frequency of worker concerns regarding fatigue and the work scheduling practices that are common during outages, the incidence of impairment from fatigue is likely to be greater than the very low incidence of

drug and alcohol use that is detected through testing. Therefore, the NRC considers the reporting of information pertaining to licensee management of worker fatigue to be consistent with the requirements for reporting information pertaining to drug and alcohol testing, the performance objective of this rulemaking for licensees to implement a comprehensive FFD program, and the NRC's belief that the management of worker fatigue is no less important to worker FFD than the effective detection and deterrence of drug and alcohol use.

- Public confidence—Public interest groups such as the UCS and the Project on Government Oversight have commented at public meetings that relevant information regarding worker fatigue is withheld to either protect alleger identity or, in the case of security personnel, plant security. In addition, several public media articles have been published during the past 2 years reporting instances of guards sleeping and guards fearing repercussions for refusing forced and excessive overtime. Information submitted by licensees in the annual reports will be publicly available and will reassure public stakeholders that the NRC is appropriately cognizant of licensee actions regarding fatigue management and that the NRC's oversight of these activities is transparent to all stakeholders.
- The burden is limited and justified—Section 26.203(e) requires licensees to report information concerning waiver use and fatigue assessments as part of the annual FFD program report. As a result, the burden associated with this reporting requirement is an incremental change to the reporting requirement for drug and alcohol testing. In addition, the fatigue management information required by § 26.203(e) is largely information that licensees will have already generated to demonstrate compliance with other provisions of Subpart I. As a result, the burden associated with the report will be largely associated with compiling the information in an appropriate form and reviewing

that compilation. The NRC has reviewed the public comments suggesting that the agency underestimated the number of clerical and management hours associated with this requirement and has taken these comments into consideration in estimating the burden of the reporting requirements in § 26.203(e) of the final rule. Nevertheless, the NRC considers the burden associated with the annual reporting requirements to be justified for the reasons described in this and the preceding paragraphs.

The NRC also considered comments that the reporting requirement ignores significant duplication in licensee efforts. The NRC agrees that § 26.205(e) of the final rule requires licensees to periodically review and assess the effectiveness of the work hour controls and that the licensee's corrective action program, which is routinely inspected by the NRC, will document and trend these reviews. However, as noted previously, the NRC considers the annual reports to be a limited burden that will enable the NRC to provide more effective and consistent oversight and achieve other objectives for the effective implementation of the requirements in Subpart I.

Public Comments on FFD Programs for Construction and Manufacturing

In response to substantive public comments and industry efforts to develop guidance on the subject, the NRC has added Subpart K [FFD Programs for Construction] to the final rule to clarify § 26.3(e) of the proposed rule, which contained requirements for combined license holders, combined license applicants, construction permit holders, construction permit applicants, as well as manufacturing license holders under Part 52.

Subpart K's FFD program is intended to provide reasonable assurance that individuals involved in the construction of a nuclear power plant who perform specified duties at the site are fit for duty, trustworthy, and reliable, commensurate with the potential risks to public health and safety and the common defense and security that their activities and access to certain information would pose.

Proposed § 26.3(e) would have retained and updated the requirements of § 26.2(c) of the former rule, while expanding the scope to include combined license holders. However, proposed § 26.3(e) would not have revised the basic approach taken in former § 26.2(c). The former rule specified that only certain regulations in Part 26 applied to licensees holding permits to construct a nuclear power plant. Section 26.2(c) of the former rule required each construction permit holder with a plant under active construction to comply with §§ 26.10 [General performance objectives], 26.20 [Written policy and procedures], 26.23 [Contractors and vendors], 26.70 [Inspections], and 26.73 [Reporting requirements] of the former rule. This provision also explained that permit holders with plants under active construction were required to implement a chemical testing program, including random tests, and make provisions for employee assistance programs, imposition of sanctions, appeals procedures, the protection of information, and recordkeeping.

Proposed § 26.3(e) would have reflected the NRC's new combined licensing procedure for nuclear power plants under 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants." It specified the entities that are regulated by the NRC (specifically, combined operating license holders before the Commission has made the finding under § 52.103 [Operation under a combined license], combined license applicants who have received authorization to construct under § 50.10(e)(3), construction permit holders under Part 50, "Domestic Licensing of Production and Utilization Facilities," construction permit applicants who have received authorization to construct under § 50.10(e)(3), and holders of manufacturing licenses under Part 52) that would be responsible for meeting certain Part 26 requirements.

The proposed rule would have replaced the cross-references to other sections of the former rule with updated cross-references to the related sections in the proposed rule (i.e., §§ 26.23 [Performance objectives], 26.41 [Audits and corrective action], and 26.189

[Determination of fitness]). The proposed rule would also have stipulated that the specified entities should implement a drug and alcohol testing program, including random testing, and make provisions for employee assistance programs, imposition of sanctions, procedures for the objective and impartial review of authorization decisions, protection of information, and recordkeeping. However, the proposed rule did not specify in detail how the FFD programs of the entities listed in proposed § 26.3(e) were to address these topics or the categories of workers who would be subject to the programs.

Some comments received during the public comment period stated that the proposed rule did not clearly describe the type of FFD programs the NRC expected under proposed § 26.3(e). Commenters stated that because the proposed rule required FFD programs for construction to comply with a few specific sections of the rule, it would have imposed virtually all of the rule's requirements on FFD programs for construction, because it would be difficult to ensure compliance with the referenced sections of the rule without applying the entire rule. Other comments received from industry representatives during the public comment period indicated that the NRC should not require FFD programs for construction that are more rigorous than industrial safety programs implemented during construction of other large, commercial facilities because construction activities do not pose risks to public health and safety or the common defense and security until nuclear fuel arrives on site. In response to these comments, the NRC staff gathered additional information about FFD programs for construction in other industries, developed a new Subpart K, "FFD Programs for Construction," and revised other sections of the rule to clarify the scope of requirements for construction activities.

The results of the NRC staff's benchmarking activities indicated that, as a result of the higher incidence of substance problems among construction workers than other occupational groups, pre-employment, for-cause, and post-accident drug and alcohol testing are increasingly common at large, commercial construction projects and some labor union coalitions have

implemented drug and alcohol testing and substance abuse treatment-referral programs for their members. In addition, the staff also identified several private-sector entities in the petrochemical and steel manufacturing industries that require drug and alcohol testing, including random testing, for construction workers on large projects, as well as employment history evaluations and other background checks. Where safety and/or security during construction are critical, large construction projects initiated by some Federal agencies (e.g., the Department of Energy) require drug and alcohol testing, including random testing, extensive background checks, and continuous behavioral observation for the most sensitive construction tasks. The NRC concluded that (1) implementing FFD requirements for new nuclear power plant construction activities is consistent with the practices of other industries, and (2) taking a graded approach to FFD requirements, by imposing requirements that are commensurate with the potential risks to public health and safety and the common defense and security that the results of construction activities may pose when a plant begins operations, is consistent with the approach implemented by other government agencies when constructing facilities that have the potential to affect public health and safety or the common defense and security.

The NRC also determined that some of the requirements in proposed § 26.3(e) would be difficult to implement. For example, much of the nuclear power plant construction workforce will likely be transient and rapidly changing. As a result, it may be challenging to conduct random drug and alcohol testing in a manner that would meet all of the random testing requirements Part 26 includes for operating plants. In addition, some new reactors will be constructed near an operating plant that has readily accessible FFD program resources, such as a specimen collection and alcohol testing site, a licensee testing facility, an FFD training program, and expert staff (e.g., a substance abuse expert, MRO, or EAP representative). However, other new reactors may be constructed at locations that are distant from the FFD program resources of an operating plant. Therefore, the NRC concluded that applying some of

the requirements in the proposed rule would be overly burdensome, such as requiring random testing of all construction workers, the requirement for all nuclear power plant construction workers to have access to an employee assistance program, and the proposed requirement for a determination of fitness process performed by a substance abuse expert under § 26.189 of the final rule.

To streamline administration of the FFD program for construction, add flexibility, and implement an approach that is commensurate with the potential risks resulting from new plant construction, the final rule requires two different levels of FFD requirements for workers in different job roles. Because of their important oversight responsibilities, the first category of workers includes quality assurance/quality control personnel, personnel who certify that inspections, tests, and analyses have met acceptance criteria (ITAACs), individuals who serve as security officers under NRC requirements, and any persons who are designated by the FFD program to perform fitness monitoring. These individuals must be subject to a full FFD program that meets the same requirements as FFD programs for operating plants (including random drug and alcohol testing at the 50 percent annual rate, behavioral observation training, and a suitable inquiry/employment history check) when they are performing duties at the location where the nuclear power plant is being constructed and will operate.

In contrast, the FFD program in Subpart K applies only to persons who will construct, at the location where the nuclear power plant will be constructed and operated, safety- and security-related structures, systems, and components (SSCs) that are required to be described in the COL/CP applicant's or permit holder's site safety analysis report, preliminary or final safety analysis report, or physical security or safeguards contingency plans (under Part 73). These workers' tasks include fabricating, erecting, integrating, and testing safety- and security-related SSCs and installing their foundations, including the placement of concrete. At a minimum, these individuals must be subject to an FFD program that meets the requirements of

Subpart K, which emphasizes performance objectives and does not incorporate all of the requirements of Part 26, unless the licensee or other entity chooses to subject them to an FFD program that meets the Part 26 requirements for operating plants, except the fatigue management requirements in Subpart I of the final rule.

If a licensee or other entity specified in § 26.3(c) of the final rule chooses to implement an FFD program for construction under Subpart K, the entity must submit to the NRC for review and approval an FFD program plan, including a written FFD policy that will be given to all individuals covered by the program and FFD procedures. The program must include pre-assignment, for-cause, and post-accident drug and alcohol testing. Subpart K requires an FFD program for construction to include sanctions for FFD policy violations, a system of files and procedures to protect personal information, and procedures for reviewing determinations that an individual has violated the FFD policy. The entity who elects to implement a program under Subpart K must conduct periodic audits, maintain records, provide reports to the NRC, and develop and apply procedures for suitability and fitness evaluations to determine whether to assign individuals to constructing safety- and security-related SSCs.

To detect and deter substance abuse by individuals who are constructing safety- and security-related SSCs, Subpart K of the final rule permits applicants for and holders of a COL or CP to subject these individuals either to random testing for drugs and alcohol or a fitness monitoring program. Subpart K also permits FFD programs for construction to—

(1) Collect specimens other than urine for drug testing and/or rely on collection sites at local hospitals or clinics that conduct testing under U.S. DOT procedures, rather than those specified in Subpart E, “Collecting Specimens for Testing,” of Part 26;

(2) Rely on healthcare professionals other than a substance abuse expert to evaluate an individual’s fitness;

(3) Designate the persons who will perform fitness monitoring, if the entity elects this option,

and adjust the number of fitness monitors performing monitoring and the frequency of monitoring to accommodate the stage of construction and local conditions; and

(4) Establish the random testing rate and limit the selection of individuals for testing to only those who are present and constructing safety- or security-related SSCs on a given day, if the entity elects this option.

In the course of its analysis and development of Subpart K of the final rule, the NRC published a *Federal Register* notice (71 FR 13782; March 17, 2006) that described the NRC's alternative concepts for FFD programs during construction and announced a meeting to obtain stakeholder feedback. The concepts described included a requirement for FFD policies and procedures on a limited set of topics; pre-access drug and alcohol testing, for-cause drug and alcohol testing, and post-event testing for accidents; requirements for protection of information; requirements for collecting specimens and conducting alcohol tests; the option to test specimens at a licensee testing facility; initial and confirmatory testing of urine specimens for drugs and validity at an HHS-certified laboratory; a review of drug test results by a medical review officer (MRO); and annual reports of FFD program performance. The notice listed fatigue management requirements, random drug and alcohol testing, the requirement for an employee assistance program, and the determination of fitness process described in the proposed Part 26 rule as concepts the NRC was not currently pursuing for FFD programs for construction. These concepts, along with draft guidance for construction programs being prepared by nuclear industry representatives, were discussed at the public meeting held on March 29, 2006.

On October 24, 2006, the NRC published the entire draft final rule text of 10 CFR Part 26 on the NRC's rulemaking website and, on November 7, 2006, held a second public meeting with stakeholders to present the technical basis for Subpart K and to describe the fitness monitoring option included in Subpart K as an alternative to random drug and alcohol testing of

construction workers. The NRC staff described four primary reasons for imposing regulatory requirements for FFD programs during construction: (1) the quality of work could be adversely affected by construction workers who are impaired by substance abuse where studies indicate that members of this group have the highest rates of substance abuse problems among occupational groups in the U.S. (e.g., Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services' National Household Survey on Drug Abuse (NHSDA) covering the years 2000-2001), (2) individuals who have become addicted to illegal drugs are susceptible to coercion and will interact with others involved in the drug trade, (3) past experience has demonstrated that errors during construction can adversely affect subsequent plant operations (NUREG/CR-6819, Vols. 1-4, "Common-Cause Failure Event Insights," (May 2003) and NUREG-1837, "Regulatory Effectiveness Assessment of Generic Issue 43 and Generic Letter 88-14," (October, 2005)), and (4) quality assurance by design uses a sampling process. The staff stated that, despite having a high degree of confidence in the effectiveness of quality assurance/quality control programs (required under 10 CFR Part 50) and the inspections, tests, analyses, and acceptance criteria (ITAAC) programs (required under 10 CFR Part 52) to detect construction errors, it is prudent to require an FFD program during construction to provide reasonable assurance that impaired construction workers do not introduce faults in safety- or security-related SSCs that may cause the SSCs to fail when the plant is operational. In addition, the staff expressed concern that some construction personnel who have substance abuse problems will have access to sensitive information that could be useful to an adversary, as well as physical access to safety- and security-related SSCs that may provide opportunities for malicious acts.

The staff acknowledged, in part, that the full defense-in-depth approach of the FFD program for operating plants is not appropriate for all construction workers because many construction activities do not have the potential to impact subsequent plant operations, and,

before fuel arrives on site, do not impose immediate radiological risks. The staff stated that, therefore, the rule's requirements for construction require a full FFD program for only a limited number of personnel who have critical oversight responsibilities for verifying that safety- and security-related SSCs are constructed properly. For workers who will construct the safety- and security-related SSCs, the FFD program requirements in Subpart K are less stringent. For example, Subpart K does not require a suitable inquiry/employment history check for these workers. In addition, the staff acknowledged the many complex logistical challenges associated with implementing FFD requirements during construction. Therefore, the Subpart K requirements provide applicants for and holders of COLs and CPs greater flexibility in implementing FFD programs for construction than the rule permits for FFD programs at operating plants.

The staff also stated that the NRC has decided to defer adopting requirements for reactor manufacturing facilities in the final rule. Although proposed § 26.3(e) would have covered these facilities, the NRC has concluded that it needs additional information before proceeding with FFD requirements for these facilities.

Stakeholder responses to the staff's presentation varied. Industry stakeholders asserted that Part 26 requirements during nuclear power plant construction are not warranted until shortly before fuel arrives on site. Industry stakeholders also commented that the fitness monitoring program, which is permitted under Subpart K in lieu of random drug and alcohol testing of workers who are constructing safety- and security-related SSCs, is an unfamiliar concept and asked several implementation questions. The staff indicated that it will work with stakeholders to develop a guidance document that would provide examples of acceptable means to implement an FFD program under Subpart K, including fitness monitoring.

A representative from a public interest group stated that the Subpart K requirements are necessary for FFD during construction. However, this representative questioned the staff's

concerns about construction workers having unfettered access to sensitive information as partial justification for the FFD requirements before fuel receipt. This individual stated that safety considerations alone, independent of any potential security concerns, warrant regulations for FFD programs for construction before fuel receipt.

The NRC believes that the requirements for FFD programs for construction in Subpart K of the final rule (1) provide reasonable assurance that individuals who are responsible for constructing and assuring the quality of safety- and security-related SSCs are fit for duty, trustworthy, and reliable, commensurate with the potential risk to public health and safety and the common defense and security, (2) permit licensees and other entities the flexibility to implement programs that are appropriate for local circumstances and the challenges created by a large and transient workforce, and (3) ensure that the privacy and other rights (including due process) of individuals who are subject to the requirements will be protected.

Public Comment on Drug and Alcohol Testing Provisions

The NRC received several detailed comments on the drug and alcohol testing provisions contained in Subparts E, F, and G. Most significantly, no comments disagreed with NRC's proposed inclusion of specimen validity testing of all urine specimens collected under Part 26 provisions. Most comments related to improving the clarity and intent of the proposed rule. Many comments received were of a technical nature and addressed inconsistencies between the NRC's proposed rule and requirements in other federal testing programs, mainly the HHS's Mandatory Guidelines for Federal Workplace Drug Testing and DOT drug and alcohol testing regulations(49 CFR Part 40). The NRC, in large part, agrees with many of the comments and has made clarifying revisions to the final rule.

Stakeholder commenters raised several concerns relating to the drug and alcohol provisions of the proposed rule. First, numerous comments were received on the validity testing provisions for screening and initial validity tests conducted at licensee testing facilities.

Some stakeholders disagreed with the NRC's proposal to permit licensee testing facilities to use point-of-collection type tests to conduct validity screening tests. The NRC considered the comments, but has retained in the final rule the proposed provision to allow licensee testing facilities to use point-of-collection type tests to conduct validity screening tests. However, in response to the comments received, the NRC has revised the performance testing provisions in § 26.137 to ensure that the functional capabilities of the performance testing of screening tests meet the criteria of the final rule. In addition, another set of comments pointed out that the proposed rule did not afford licensee testing facilities the opportunity to conducting specific gravity testing on specimens, which is a required component of reporting specimens as dilute, substituted, or invalid. The NRC continues to believe that any specimen that has a creatinine concentration below 20 mg/dL must be forwarded for additional testing at an HHS certified laboratory (including specific gravity testing). Finally, the NRC received numerous comments on the use of the term "non-negative." Some commenters believed that the term created significant confusion with respect to understanding specimen test results. The NRC agrees with the commenters and has replaced the term "non-negative test result" in the final rule with the term “positive” (for drug test results) and the term “adulterated, substituted, and invalid” (for validity test results). In addition, the NRC has replaced the term "non-negative test result" with the new term "questionable validity" for licensee testing facility test results that indicate that a specimen may be adulterated, substituted, dilute, or invalid.

VI. Section-by-Section Analysis of Substantive Changes

The final rule is organized into twelve 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 - [Reserved]

Subpart K - FFD Programs for Construction

Subpart L - [Reserved]

Subpart M - [Reserved]

Subpart N - Recordkeeping and Reporting Requirements

Subpart O - Inspections, Violations, and Penalties

A detailed cross-reference table between the former and final Part 26 provisions is included at the end of this document.

The NRC has deleted Appendix A of the former rule and moved the detailed requirements for conducting drug and alcohol testing that were contained in Appendix A to

10 CFR Part 26 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 final rule.

Subpart A – Administrative Provisions

Section 26.1 Purpose.

Section 26.1 [Purpose] of the final rule amends the language of the corresponding section of the former rule. The final rule deletes the term "certain aspects" and adds the term "implementation" to the phrase in the former rule which stated, "for the establishment and maintenance of * * * fitness-for-duty programs," in order to convey more accurately that the final rule includes requirements for implementing FFD programs, in addition to requirements for establishing and maintaining such programs. The NRC has moved the portion of former § 26.1 that referred to the entities who are subject to the rule to § 26.3 [Scope] in order to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the final rule, by consolidating related requirements into one section.

Section 26.3 Scope.

The NRC has reorganized, renumbered, and amended § 26.3 relative to both former § 26.2 [Scope] and proposed § 26.3 [Scope] based upon NRC's consideration of issues raised by public comments on the proposed rule. In general, the final rule retains and clarifies most of the provisions pertaining to the scope of the former and proposed rules. However, one public comment stated that the proposed rule was confusing with regard to the entities and individuals who are subject to the different requirements of this part. Therefore, the final rule amends this section of the proposed and former rules and adds a new § 26.4 [FFD program applicability to categories of individuals], as discussed with respect to that section, to clarify the rule text. Also,

the final rule makes a substantive change to the proposed rule by adding § 26.3(c), which modifies the requirements of proposed § 26.3(e) pertaining to combined license holders and applicants and construction permit holders and applicants. As in § 26.3(e) of the proposed rule, § 26.3(c) of the final rule specifies the requirements to which these entities are subject. However, the final rule modifies these requirements and moves them to a new Subpart K [FFD Programs for Construction]. These changes are discussed in more detail with respect to § 26.3(c).

Section 26.3(a) of the final rule specifies that licensed nuclear power reactor operators and combined operating license holders after the Commission has made the finding in § 52.103(g) shall comply with the requirements of this part, with the exception of Subpart K [FFD Programs for Construction]. Combined operating license holders shall also comply with the requirements of this part, with the exception of Subpart K, to be consistent with the revised 10 CFR Part 52 licensing process for new reactors.

With respect to the proposed rule, the final rule adds a reference to paragraph (g) of 10 CFR 52.103 to § 26.3(a) for greater accuracy. The final rule also clarifies that the regulations contained in Subpart K [FFD Programs for Construction] do not apply to the licensees and other entities specified in § 26.3(a) because only combined license holders before the Commission has made the finding under § 52.103(g) or combined license applicants and construction permit holders or applicants are permitted to implement an FFD program under the more flexible program requirements in Subpart K, as specified in § 26.3(c). The final rule also adds a requirement that an FFD program meeting all of the requirements of Part 26 except Subpart K must be implemented before receipt of special nuclear material in the form of fuel assemblies. The NRC believes that once fuel assemblies have arrived onsite, the full range of potential risks to public health and safety and the common defense and security that Part 26 is designed to avert are possible. Therefore, the NRC believes that a more rigorous

FFD program must be in place at this time.

Section 26.3(b) of the final rule combines § 26.3(b) and (c) of the proposed rule. This section retains the requirement in the first sentence of former § 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. Section 26.3(b) also retains the requirements of former § 26.2(d) that specified that entities other than a corporation are subject to the regulations of this part 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.

However, the entities specified in this paragraph are not subject to the requirements contained in Subpart I [Managing Fatigue] for the reasons that are discussed with respect to § 26.201 [Applicability]. With respect to the proposed rule, the final rule adds a specification that the entities listed in § 26.3(b) are not subject to the requirements contained in Subpart K [FFD Programs for Construction], because the requirements of Subpart K apply only to combined license holders before the Commission has made the finding under § 52.103(g) or combined license applicants and construction permit holders or applicants during construction, as specified in § 26.3(c). The provision also eliminates the cross reference to § 26.25(a)(3) of the proposed rule because the final rule has moved the proposed provisions in § 26.25 to § 26.4 of the final rule for increased clarity in the rule's organization.

Section 26.3(c) of the final rule retains but modifies the provisions of former § 26.2(c) and proposed § 26.3(e). Like the proposed rule, the final rule specifies the requirements that are applicable to combined license holders (under Part 52 of this Chapter) before the Commission has made the finding under § 52.103 of this chapter; construction permit holders (under Part 50 of this chapter); and construction permit and combined license applicants who

have received the authorization to construct under § 50.10(e)(3) of this chapter. Proposed § 26.3(e) had retained and updated the requirements of § 26.2(c) of the former rule, while expanding the scope of FFD programs at reactor construction sites to include combined license holders. However, proposed § 26.3(e) did not revise the basic approach taken in § 26.2(c), and specified that only certain regulations in Part 26 applied to the entities listed in this paragraph. This provision specifies that the entities listed are subject to certain requirements of Part 26, except Subpart I.

The NRC received a public comment, discussed in detail in Section V of this document, which argued that the proposed § 26.3(e) was unclear regarding the type of FFD program the NRC expected from the licensees specified in this paragraph. The NRC acknowledged these concerns, and for the reasons discussed in Section V of this document, the final rule amends the requirements of proposed § 26.3(e) and moves them to a separate Subpart K [FFD Programs for Construction]. The specific requirements applicable to the entities specified in § 26.3(c) are discussed in this document with respect to Subpart K.

The NRC has decided to defer adopting requirements for reactor manufacturing facilities. Although these facilities would have been covered under proposed § 26.3(e), the agency has concluded that it needs additional information before going forward with FFD requirements for such facilities, particularly when FFD requirements are closely linked to issues of access authorization and physical security. The NRC is considering, but has not yet completed, regulatory requirements on those subjects for reactor manufacturing facilities. Any industry stakeholders with a potential interest in pursuing a license for a reactor manufacturing facility should ensure that they engage in early discussions with the NRC so that suitable requirements can be developed in a timely manner.

Section 26.3(d) of the final rule retains the meaning of a portion of former § 26.23(a)(1). The final rule requires that a C/V FFD program meet the standards of this part if licensees rely

upon the C/V's FFD program to meet the requirements of this part, but amends some of the terminology used in the former rule. The provision adds C/Vs to the list of entities who are subject to Part 26 in § 26.3 to more clearly convey that C/Vs may be directly subject to NRC inspection and enforcement actions than the former rule language implied. The former rule text presented 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, former § 26.23(a)(1) stated, "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 former 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, § 26.3(c) of the final rule includes C/V FFD programs and program elements upon which the licensees and other entities specified in paragraphs (a) through (c) of this section rely within this section to convey more accurately that C/Vs are directly accountable for meeting the applicable requirements of Part 26, not 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 final rule because some provisions of the rule apply only to C/Vs, including, but not limited to § 26.717(g). The final rule makes this change to meet Goal 6 of the rulemaking to improve the clarity in the organization and language of the rule.

The phrases "program elements" and "licensees and other entities specified in paragraphs (a) through (c) of this section" are used in § 26.3(d) of the final rule because C/Vs 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 final rule except drug and alcohol testing. In this case, the rule does 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 final 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 § 26.31(c) [Conditions for testing], such as for cause testing, and a licensee or other entity specified in paragraphs (a) through (c) of this section relies upon the results of the C/V's tests in determining whether to grant authorization to an individual (see Subpart C [Granting and Maintaining Authorization]), then the use of these phrases in the provision would be correctly interpreted to mean that the C/V's drug and alcohol testing program element must meet the final rule's requirements related to drug and alcohol testing when conducting the tests on which the licensee or other entity relies. In 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 specified in paragraphs (a) through (c) of this section, then the provision does not require the C/V to meet the applicable Part 26 requirements for that FFD program element. Section 26.3(d) requires C/Vs to meet the requirements of Subpart I [Managing Fatigue] of the final rule, if any nuclear power reactor licensees specified in paragraphs (a) through (c) of this section rely upon a C/V's fatigue management program element to meet the requirements of Subpart I. The applicability of Subpart I to C/Vs is discussed with respect to § 26.201 [Applicability].

The NRC has either eliminated or moved to other places of the final rule other provisions of former § 26.23 [Contractors and vendors]. The NRC has moved the former requirement for licensees to retain written agreements with C/Vs in the second sentence of § 26.23 to Subpart N [Recordkeeping and Reporting Requirements] of the final rule. The NRC has moved the requirement in former § 26.23(a)(1) to Subpart C [Granting and Maintaining

Authorization] of the final rule. That provision 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. The NRC has addressed the audit requirement contained in former § 26.23(b) in § 26.41(d) [Contracts] of the final rule. By moving the former requirements to different sections of the final rule and grouping related requirements together in one section or subpart that addresses similar topics, the NRC has met Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has amended and moved the requirements of proposed § 26.3(e) to § 26.3(c) and Subpart K [FFD Programs for Construction] of the final rule. The requirements contained in proposed § 26.3(e) are discussed in this document with regard to those sections.

Section 26.3(e) of the final rule retains the second sentence of former § 26.2(b) and addresses entities who are not subject to the rule. The NRC has moved the first sentence of former § 26.2(b), which addressed individuals who are not subject to the rule, to § 26.4 [FFD program applicability to categories of individuals] of the final rule for organizational clarity.

Section 26.4 FFD program applicability to categories of individuals.

In the proposed rule, the NRC moved the provisions in former § 26.2 [Scope] that specified the individuals whose duties require them to be subject to the rule and exempt certain other individuals to § 26.25 [Individuals subject to the fitness-for-duty program]. However, the NRC has deleted § 26.25 from the final rule, and has amended, reorganized, and moved all of the provisions in proposed § 26.25 to a new § 26.4 [FFD program applicability to categories of individuals] to group related applicability requirements together in one section.

The provisions moved into new § 26.4 include the second sentence of former § 26.2(a), the first sentence of former § 26.2(b), and the portion of the second sentence of former § 26.2(d) that pertained 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 makes the two sets of provisions easier to locate within the final rule without compromising the intended meaning of these provisions. Also, moving the applicability requirements for individuals into Subpart A from Subpart B, where they were located in the proposed rule, is appropriate because some categories of individuals who are subject to the rule are not subject to Subpart B of the final rule. Therefore, the applicability requirements in § 26.4 clearly specify the categories of individuals who are subject to Part 26. The NRC determined that grouping all of the applicability requirements into one subpart of the final rule increases the ease of locating these provisions, consistent with Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.4(a) of the final rule retains portions of proposed § 26.25(a)(1). Proposed § 26.25(a)(1) amended portions of former § 26.2(a) and (d) and described the individuals whose duties require them to be subject to Part 26. The final rule specifies that the persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and who perform the duties in § 26.4(a)(1) through (a)(5) shall be subject to an FFD program that meets the requirements of this part, including Subpart I [Managing Fatigue]. The NRC has moved the categories of individuals specified in § 26.199(a)(1) through (a)(5) of the proposed rule to § 26.4(a)(1) through (a)(5) of the final rule in order to group together all related applicability requirements for individuals in one section. This change is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. Additional concerns regarding the reasons why individuals performing these duties shall be subject to the fatigue management provisions of Subpart I are discussed with respect to § 26.205(a) [Individuals subject to work hour controls]. The final rule clarifies that these individuals may not be subject to the more flexible FFD program described in Subpart K [FFD Programs for

Construction] because they are granted unescorted access by the licensees in § 26.3(a), to whom all of the requirements of this part, except Subpart K, apply.

Section 26.4(b) of the final rule retains portions of and amends proposed § 26.25(a)(1). The final rule adds § 26.4(b) to clarify that individuals who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a), including those who do not perform the duties described in paragraph (a) of this section, shall be subject to an FFD program that meets all of the requirements of this part, except § 26.205 [Work hours] and Subpart K [FFD Programs for Construction]. Just as in paragraph (a) of this section, § 26.4(b) does not permit these individuals to be subject to an FFD program that meets the more flexible requirements of Subpart K because they are granted unescorted access to protected areas by the licensees in § 26.3(a), to whom all of the requirements of this part, except Subpart K, apply. This paragraph does not require the individuals in this paragraph to be subject to an FFD program that meets the requirements of § 26.205 for the reasons discussed with regard to § 26.205(a).

Section 26.4(c) of the final rule retains and amends proposed § 26.25(a)(2). Proposed § 26.25(a)(2) amended portions of former § 26.2(a) and (d) and described the individuals whose duties require them to be subject to Part 26. Section 26.4(c) of the final rule clarifies that all persons who are required by a licensee in § 26.3(a) to physically report to the licensee's Technical Support Center or Emergency Operations Facility shall be subject to an FFD program that meets all of the requirements of this part, except § 26.205 [Work hours] and Subpart K [FFD Programs for Construction]. Just as in paragraphs (a) and (b) of this section, § 26.4(c) of the final rule does not permit these individuals to be subject to an FFD program that meets the more flexible requirements of Subpart K because they are granted unescorted access by the licensees in § 26.3(a), to whom all of the requirements of this part, except Subpart K, apply. This paragraph also does not require the specified individuals to be subject to an FFD program

that meets the requirements of § 26.205 for the reasons discussed with regard to § 26.205(a).

Section 26.4(d) of the final rule retains and amends portions of the provisions of proposed § 26.25(a)(3). Proposed § 26.25(a)(3) amended the portions of former § 26.2(a) and (d) and described the individuals whose duties require them to be subject to Part 26. Section 26.4(d) of the final rule specifies that any individual whose duties for the licensee and other entities in § 26.3(b) require him or her to have the types of access or perform the activities in paragraphs (d)(1) through (d)(5) shall be subject to an FFD program that meets all of the requirements of this part, except Subparts I [Managing Fatigue] and K [FFD Programs for Construction]. Section 26.4(d) of the final rule does not require these individuals to be subject to an FFD program that meets the requirements of Subparts I or K, which is consistent with the provisions of the proposed rule.

The NRC has added § 26.4(e) to the final rule to specify the individuals involved in the construction of a new reactor plant who must be subject to a rigorous FFD program that complies with the requirements of Part 26, except for the requirements of Subparts I and K. These individuals include all individuals whose activities at the location where the nuclear power plant will be constructed and operated require them to serve as security officer under NRC requirements, perform quality assurance activities as specified in Appendix B to part 50, determine that inspections, tests, and analyses, or parts thereof, required under part 52 of this chapter have been successfully completed, or are designated under § 26.406 by a licensee or other entity to monitor the fitness of the individuals specified in paragraph (f) of this section. These individuals have direct responsibility for assuring the quality and security of construction activities and, thereby, the safety and security of the completed nuclear power plant. The NRC considers it prudent that these personnel are verified to be trustworthy and reliable, as demonstrated by the avoidance of substance abuse, and fit for duty with an FFD program that is equivalent to the program required for an operating plant, which includes a 50 percent

random testing rate and a suitable inquiry and employment history check.

The NRC has added § 26.4(f) to the final rule to specify the individuals involved in the construction of a new reactor plant who, at the licensee's or other entity's discretion, must be subject to either a more flexible FFD program under Subpart K, or a more rigorous FFD program that meets the requirements in the other portions of Part 26 except Subparts I and K. These individuals include any individual who is constructing safety- or security-related SSCs at the location where the nuclear power plant will be constructed and operated. (Definitions of safety- and security-related SSCs are provided in § 26.5 and discussed with respect to that section.) These tasks include fabricating, erecting, integrating, and testing safety- or security-related SSCs and the installation of their foundations, including the placement of concrete.

The NRC determined that it is necessary to impose FFD requirements on individuals who are constructing safety- or security-related SSCs because (1) the quality of work could be adversely affected by construction workers who are impaired by substance abuse where studies indicate that members of this group have the highest rates of substance abuse problems among occupational groups in the U.S. (e.g., Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services' National Household Survey on Drug Abuse (NHSDA) covering the years 2000-2001), (2) individuals who have become addicted to illegal drugs are susceptible to coercion and will interact with others involved in the drug trade, (3) past experience has demonstrated that errors during construction can adversely affect subsequent plant operations (NUREG/CR-6819, Vols. 1-4, "Common-Cause Failure Event Insights," (May 2003) and NUREG-1837, "Regulatory Effectiveness Assessment of Generic Issue 43 and Generic Letter 88-14," (October 2005)), and (4) quality assurance by design uses a sampling process. Despite having a high degree of confidence in the effectiveness of quality assurance and ITAAC programs to detect construction errors, the NRC believes it is prudent to require an FFD program during construction to provide

reasonable assurance that impaired construction workers do not introduce faults in safety- or security-related SSCs that may cause the SSCs to fail to perform their intended functions when the plant is operating. In addition, the NRC is concerned that some construction personnel who have substance abuse problems will have access to sensitive information that could be useful to an adversary, as well as physical access to safety- and security-related SSCs that may provide opportunities for malicious acts. Therefore, the NRC is requiring individuals who are directly involved in constructing safety- and security-related SSCs to be subject to an FFD program.

Section 26.4(g) of the final rule contains the provisions in proposed § 26.25(a)(4). Proposed § 26.25(a)(4) clarified the NRC's original intent that FFD program personnel must be subject to the FFD program. Although former Section 2.3 in Appendix A to Part 26 required 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. This change clarifies 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. Further, 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 also have been identified as substance abusers. Therefore, the revision to former § 26.2(a) fulfills the NRC's original objective and requires 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 in § 26.4(g)(1), including, but not limited to, the MRO; (2) make determinations of fitness in § 26.4(g)(2); (3) make authorization decisions in § 26.4(g)(3); (4) are involved in selecting or notifying individuals for testing in § 26.4(g)(4); or (5) are involved in the collection or on-site testing of specimens in § 26.4(g)(5).

Although job titles and responsibilities may differ among different Part 26 FFD programs, examples of FFD program personnel who are subject to Part 26 under the final rule include, but are not limited to, the following: the FFD program manager under § 26.4(g)(1) through (g)(5); the MRO and MRO staff under § 26.4(g)(1); the licensee's or other entity's reviewing officials under § 26.4(g)(3); specimen collectors under § 26.4(g)(5); SAEs who are under contract to or employed by the FFD program under § 26.4(g)(2); and licensee testing facility personnel under § 26.4(g)(5). 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 § 26.4(g)(4) if such personnel have knowledge of who was selected for random testing before the individual is notified or the ability to affect the selection of specific individuals for random testing.

Section 26.4(g) of the final rule amends the proposed rule to clarify the requirements

that the FFD programs specified in this paragraph must meet. The section specifies that FFD program personnel who are involved in the day-to-day operations of the program, as defined by the procedures of the licensees or other entities and whose duties require them to have the types of access and perform the activities in § 26.4(g)(1) through (g)(5) shall be subject to an FFD program that meets all of the requirements of Part 26, except Subparts I [Managing Fatigue] and K [FFD Programs for Construction], and at the licensees's discretion, Subpart C [Granting and Maintaining Authorization]. Also, with respect to the proposed rule, the final rule clarifies that the procedures referenced are those of the licensees and other entities specified in § 26.3(a), (b), and, as applicable, (c) and (d). The term "as applicable" in this provision specifies that entities listed in § 26.3(c) must subject FFD program personnel to all of the requirements of this part if they perform the activities specified in § 26.4(g). These licensees may use different FFD program personnel for a Subpart K program, in which case, those FFD program personnel would not be subject to a full program under the rule. For entities specified in § 26.3(d), C/Vs must subject their FFD program personnel to the full program only if a licensee or other entity is relying on drug and alcohol testing done under the C/V's program. The final rule also clarifies that the FFD programs for FFD program personnel performing the listed activities in § 26.4(g) must meet all the requirements of Part 26, except Subparts I and K, which is consistent with the provisions of proposed rule. The final rule clarifies that the licensees and other entities may subject FFD program personnel to an FFD program that meets the requirements of Subpart C, for the reasons discussed with respect to § 26.31(b). These clarifications are consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the final rule.

Section 26.4(h) retains and amends the requirements contained in proposed § 26.25(d). Proposed § 26.25(d) clarified that individuals who have applied for authorization to perform duties that require them to be subject to Part 26 are also subject to some provisions of the final

rule. The former Part 26 required an applicant for authorization to provide a written statement related to his or her past activities under this part in former § 26.27(a)(1); provide permission to the licensee to conduct a suitable inquiry in former § 26.27(a)(2); and submit to pre-access testing in former § 26.24(a)(1). While the proposed rule used general terms, such as "applicable requirements of this part" and "applicable protections of this part," the final rule clarifies the requirements to which the individuals listed in this paragraph are subject. The final rule requires that individuals who have applied for authorization to have the types of access or perform the activities described in paragraphs (a) through (d) of this section shall be subject to the requirements in §§ 26.31(c)(1), 26.35(b), 26.37, 26.39 and the applicable requirements of Subparts C [Granting and Maintaining Authorization], and E [Collecting Specimens for Testing] though H [Determining Fitness-for-Duty Violations and Determining Fitness]. These clarifications ensure the internal consistency of the final rule and meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.4(i)(1) through (i)(3) contains the provisions of proposed § 26.25(b)(1) through (b)(3). The final rule groups together in one paragraph the former rule's provisions that identify individuals who would not be subject to the rule. This change has been made to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.4(i)(1) to the final rule as a result of extensive discussions with industry stakeholders at the public meetings mentioned in the Section I.D of this document. Industry stakeholders expressed strong concern that the related language in the affirmed rule (which was discussed in the preamble to the proposed rule) that delineated the FFD program personnel who must be subject to 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 locations other 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 the significant logistical difficulties involved in ensuring that these individuals are subject to behavioral observation and drug and alcohol testing, and excessive costs to hire additional MRO(s) to review any positive, adulterated, substituted, or dilute 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 § 26.4(i)(1) to the final rule. The provision excludes 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 are not subject to the rule under this provision may include, but are not 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 paragraph are 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.

However, § 26.4(g) of the final rule requires MROs and SAEs to be subject to Part 26 (see the discussion of § 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 positive, adulterated, or substituted drug test result is an FFD policy violation (i.e., the MRO under § 26.185) and whether an individual is fit to safely and competently perform the 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.

Section 26.4(i)(2) and (i)(3) retains the first sentence of former § 26.2(b) but divides it into two paragraphs. This organizational change makes 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 NRC has moved the second sentence of former § 26.2(b) to § 26.3(f) of the final rule, rather than retain it in this provision, because it addressed entities who would not be subject to the rule, rather than individuals. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule adds a new § 26.4(i)(4), which specifies that FFD program personnel of a program that is regulated by another Federal agency or State upon which a licensee or other entity relies to meet the requirements of this part, as permitted in paragraph (j) of this section, are not subject to a licensee's or other entity's program if the FFD program personnel are not employed by the licensee or other entity and their normal workplace is not at the licensee's or other entity's facility.

Section 26.4(j) contains the provisions of proposed § 26.25(c). This provision provides that persons who are covered by a program regulated by another Federal agency or State need not also be covered by duplicate elements of 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 DOT's drug and alcohol testing requirements [49 CFR Part 40, 65 FR 41944, August 9, 2001]. This revision reduces 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 continues 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 are not 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 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.

Section 26.4(j)(1) through (j)(5) of the final rule contains the provisions in proposed § 26.25(c)(1) through (c)(4) and (c)(6). The final rule lists the necessary characteristics of an alternative Federal or State program that, under the final rule, licensees and other entities may rely upon to satisfy the requirements of this part for an individual who is subject both to Part 26 and an alternative program. Paragraphs 26.4(j)(1) and (j)(3) permit licensees and other entities to rely on the alternative program to meet the final rule's drug testing requirements if the alternative program tests for the drugs and drug metabolites that are specified in the final rule at or below the cutoff levels established in the final rule and an HHS-certified laboratory conducts the program's specimen validity and drug testing. Similarly, § 26.4(j)(2) permits licensees and other entities to rely on the alternative program to meet the final rule's alcohol testing requirements if the alternative program's alcohol testing procedures and devices meet the final rule's requirements and the alternative program uses cutoff levels that are at least as stringent as those specified in § 26.103(a). Section 26.4(j)(4) permits the licensee or other entity to rely on an alternative program's FFD training if that training addresses the knowledge and abilities listed in § 26.29(a)(1) through (a)(10). If the licensee or other entity relies on the alternative program, § 26.4(j)(5) requires the licensee or other entity to ensure that the alternative program informs the licensee or other entity of any FFD violations. The final rule deletes the provision that was contained in proposed § 26.25(c)(5). The proposed provision allowed individuals subject to Part 26 and to a Federal agency- or State- regulated program to be covered only by those elements of an FFD program that are not included in the Federal agency or State program if an impartial and objective procedure is provided for the review and reversal of any findings of an FFD policy violation. The NRC has deleted this provision because

it recognizes that it would be impractical to require a licensee to ensure that a Federal agency or State program would include an impartial and objective procedure for the review and reversal of any findings of an FFD policy violation. Such assurance would be beyond the licensee's ability to obtain or provide because the licensee would not control the Federal agency or State program. Therefore, this change is consistent with Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

These provisions are consistent with the former and final 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 § 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, fulfills the rule's performance objectives and improves Part 26 by eliminating or modifying unnecessary requirements, which is Goal 5 of this rulemaking. However, an important difference between the final rule's permission for licensees and other entities to rely on the programs of other Federal and State agencies, compared to the final rule's permission for licensees and other entities to rely on C/V programs, is that the final rule does not require licensees and other entities to audit the alternate Federal and State programs under § 26.41 [Audits and corrective action]. Auditing Federal and State programs is 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 is in keeping with Goal 5 of this rulemaking.

Section 26.5 Definitions.

Section 26.5 [Definitions] amends former § 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 SAMHSA and DOT); (3) define new terms used in other sections of the rule; and (4) move definitions into this section from former Section 1.2 in Appendix A to 10 CFR Part 26, which contained definitions of important terms used in Appendix A to Part 26. The rule also eliminates six terms in former § 26.3 and Section 1.2 in Appendix A to Part 26 because they are fully defined in the provisions of the final rule or are not used in the final rule. In addition, the rule eliminates redundant definitions of some terms, which appear in both former § 26.3 and Section 1.2 in Appendix A to Part 26. Finally, the NRC has revised some definitions to make them simpler and easier to understand, consistent with the NRC's commitment to using plain language. For example, some definitions in the former rule included requirements that were also contained in other sections of the rule. In these instances, the final rule eliminates the embedded requirements from within the definitions, but retains the definitions in this section. The NRC has moved these requirements to the related sections of the final rule for organizational clarity.

The final rule modifies several definitions of the proposed rule due to public comment or to increase clarity in the language of the rule, consistent with Goal 6 of the rulemaking. These changes are discussed below. Otherwise, the final rule adopts the definitions of this section as proposed, without change.

The NRC has made the majority of the changes to this section as a result of adding new requirements for urine drug testing, including specimen validity testing, to the rule. The rule incorporates 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 changes require adding terms to § 26.5, modifying a number of the terms that were used in the former rule, and revising the definitions of some terms in the former rule that are also used in the final rule, as described in the following

paragraphs.

The final rule modifies several terms that are used in the former and proposed rules 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. The final rule has deleted the term “non-negative” from the proposed rule. The NRC has added the term “non-negative” to the proposed rule to refer to any adverse test result from the different types of urine testing that are required under the final rule. However, the NRC received a public comment that requested clarification of “non-negative” with respect to “positive” in the proposed rule. Therefore, the NRC has deleted “non-negative” from the final rule and replaced it with more specific terminology. The final rule uses the term “positive” to refer to results from drug and alcohol testing indicating the presences of drugs or drug metabolites in a urine specimen or the presence of alcohol above the cutoff levels established in this part in breath or oral fluids specimens. The final rule uses the terms “adulterated, dilute, substituted, or invalid,” as appropriate, to refer to results of validity tests of urine specimens indicating that the specimen may not be normal human urine. Consequently, the NRC has replaced the term “non-negative” in the following definitions in this section: “confirmed test result,” “cutoff level,” and “Medical Review Officer (MRO).”

The final rule, with respect to both the former and proposed rules, adds the term “positive result” to specify what positive results mean for drug and alcohol testing. The definition clarifies that, when the laboratory has conducted the special analysis permitted in § 26.163(a)(2), a result reported by an HHS-certified laboratory that a specimen contains a drug or drug metabolite below the cutoff concentration is also a positive result.

The final rule also changes the former term “confirmed positive test” to “confirmed test result” to clarify that this term refers to the results of the MRO’s review of both drug and validity tests of urine specimens, rather than to a type of testing. The final rule also removes the

reference to testing of blood specimens for alcohol that is contained in the former definition of "confirmed positive test" from the definition of "confirmed test result" because blood specimens are no longer collected at the donor's request for confirmatory alcohol testing, as discussed with respect to § 26.83(a). With respect to the proposed rule, the final rule specifies that a confirmed test result demonstrates that an individual has used drugs "and/or" alcohol. The NRC has made these changes to meet Goal 6 of this rulemaking, as it relates to improving clarity in the language of the final rule.

The final rule adds several 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 terms include "adulterated specimen," "dilute specimen," "substituted specimen," and "invalid result." The final rule also adds the term "oxidizing adulterant" to refer to one class of substances that may be used to adulterate urine specimens. These new terms and definitions have been adapted from the HHS Guidelines.

With respect to the proposed rule, the final rule adds the term "questionable validity" to mean the results of validity screening or initial validity tests at a licensee testing facility indicating that a urine specimen may be adulterated, substituted, dilute, or invalid. The NRC has added this term based on the consideration identified by a commenter that licensee testing facilities may not be able to determine whether a specimen is substituted, dilute, or meets some of the invalid criteria because they are not required to test for specific gravity of a specimen. This term replaces the term "suspect specimens" in the former rule. Therefore, the NRC has made this change to improve clarity in the language of the rule, consistent with Goal 6 of this rulemaking.

The final rule also adds 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 final rule also adds 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 final rule.

The final rule changes certain terms that describe drug and alcohol tests to reflect the addition of urine specimen validity testing requirements. The changes include replacing the term “initial or screening test” with more specific terms to distinguish between drug testing and testing for urine specimen validity. The NRC has added the terms “validity screening test,” “initial drug test,” and “initial validity test” to refer to the first tests of a urine specimen that are 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 final rule modifies the proposed definition of “validity screening test” to clarify that both non-instrumented tests, in which the endpoint result is obtained by visual evaluation, and instrumented (machine read) tests are acceptable methods to determine the need for initial validity testing of urine specimen. The NRC has made these changes to improve clarity in the language of the rule, consistent with Goal 6 of this rulemaking.

The final rule also modifies the definition of “initial or screening test” in the former rule to eliminate the requirement that the test must be performed using immunoassay techniques because the NRC addresses that requirement in other sections of the rule. The final rule replaces the general term “confirmatory test” in the former rule with the more specific terms, “confirmatory drug or alcohol test” and “confirmatory validity test.” In addition, the definitions of these terms in the final rule do not include requirements for the methods to be used in performing confirmatory tests because these requirements are addressed in other sections of the rule. Therefore, the NRC has removed the requirement that confirmatory drug testing be performed using gas chromatography/mass spectrometry (GC/MS) testing from the definition. The final rule also eliminates the reference to GC/MS testing of blood samples for confirmatory

alcohol testing in the definition of “confirmatory drug or alcohol test” because the final rule does not allow donors the option to provide a blood sample for alcohol confirmatory testing, as discussed with respect to § 26.83(a).

The final rule also adds 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 NRC has adapted the definitions of these terms from the HHS Guidelines.

In addition, the final rule modifies the definitions of two terms in the former and proposed rules to be consistent with the new drug and alcohol testing terminology that is used throughout the rule. The final rule amends the definition of “cutoff level” in the former rule to clarify that the term is also applicable to the interpretation of results from specimen validity testing. The final rule further modifies this definition to refer to test results as “positive,” “of questionable validity,” and “adulterated, substituted, dilute, or invalid” to account for validity tests results from a licensee testing facility. The final rule amends the definition of “Medical Review Officer (MRO)” to refer to a “drug and validity” test result, rather than a “positive” test result, to clarify that the MRO reviews validity test results in addition to drug test results.

The rule also adds six terms that are related to the requirements contained in Subpart C [Granting and Maintaining Authorization]. The term “potentially disqualifying FFD information” refers to the types of information that licensees and other entities who are subject to the rule consider when deciding whether to grant or maintain an individual’s authorization to have the types of access or perform the duties that are listed in § 26.4. The final rule also adds 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 NRC has also added the term “best effort” 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 § 26.63(a).

The final rule, with respect to the proposed rule, also adds a definition of the term “authorization” in response to public comment. The final rule uses the term, "authorization," to refer to an individual's status as having been determined by a licensee or other entity to be eligible to perform the duties or have the types of access listed in § 26.4(a) through (e), and at the licensee's or other entity's discretion, § 26.4(f) and (g) of the final rule. The agency selected this term to differentiate "authorization" under Part 26 from the terms, "unescorted access authorization" and "unescorted access," that are used by nuclear power plant licensees to refer to individuals who are subject to both Part 26 and related access authorization requirements under 10 CFR 73.56 [Personnel access authorization requirements for nuclear power plants]. The NRC created a new term because some categories of individuals who are subject to Part 26 are not required to meet the additional requirements of 10 CFR 73.56 of this chapter. For example, the NRC has not promulgated access authorization requirements in § 73.56 for FFD program personnel. Therefore, the final rule uses the term "authorization" to refer to the determination that these categories of individuals may perform the duties or have the types of access specified in § 26.4 to distinguish the requirements in this part from the additional requirements that a licensee or other entity must meet in order to grant individual "unescorted access authorization" or "unescorted access" to nuclear power plant protected areas.

The final rule also adds several terms that are necessary to implement the requirements of Subpart I [Managing Fatigue]. These terms 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 rule also uses the term “alertness” to refer to an

individual's ability to remain awake and sustain attention, which is adversely affected by fatigue. The new term "circadian variation in alertness and performance" defines a factor that licensees would consider when conducting a fatigue assessment under § 26.211 [Fatigue assessments]. The final rule also adds the term "increased threat condition" to refer to circumstances in which the rule provides licensees with some flexibility in implementing the work hour controls of § 26.205 [Work hour controls]. With respect to the proposed rule, the final rule modifies the term "increased threat condition" to clarify that any increase in the protective measure level is relative to the lowest protective measure applicable to the site during the previous 60 days.

The final rule, with respect to the proposed rule, adds a definition of "shift cycle" to mean a series of consecutive work shifts and days off that is planned by the licensee or other entity to repeat regularly, thereby constituting a continuous shift schedule. Similarly, the final rule adds "8-hour shift schedule," "10-hour shift schedule," and "12-hour shift schedule" to define these schedules in terms of allowable hours of a workday averaged over a shift cycle.

Also, the NRC has added the term "unit outage" to the final rule to clarify that the specific reactor unit has to be disconnected from the electrical grid to be declared in an outage. This term was added in response to stakeholder comment raised at a public meeting on whether, for purposes of implementing the work hour controls, a unit was considered to be in an outage if reactor power was reduced for repair or maintenance of a system or component, but the reactor was not shutdown. Consequently, the NRC defined unit outage as the reactor being disconnected from the electrical grid. This definition provides a clearly identifiable plant state for applying the work hour controls in § 26.205(d)(4) and (d)(5).

The term "directing" clarifies new requirements for MRO staff under § 26.183(d) and the scope of individuals who would be subject to work hour controls in § 26.205 [Work hours]. The NRC has revised this definition in response to public comment regarding the lack of clarity of the term "directing" as used in Subpart I in the proposed rule and the scope of personnel that

should be subject to work hour controls. Specific comments included remarks regarding the scope of engineering functions that should or should not be subject to work hour controls. The revised definition in the final rule clarifies the NRC's expectations that a limited scope of personnel providing technical input would be subject to the requirements of § 26.205. The definition explicitly states the criteria that the term “directing” refers to an individual who is directly involved “in the execution of the work activity” or “is ultimately responsible for the correct performance of that work activity” as opposed to, for example, the planning, development or scheduling of the activity, and that the technical input does not receive “subsequent technical review.” The NRC believes that, in the context of Subpart I, the revised definition more clearly focuses on activities that have the potential to substantively and immediately affect safety. These changes are consistent with the changes that the NRC has made to the final rule in Subpart I and meet Goal 6 of this rulemaking as it relates to improving clarity in the language of the rule.

The final rule, with respect to the proposed rule, also adds several terms that are necessary to interpret and implement the requirements in Subpart K [FFD Programs for Construction]. The final rule includes definitions of “constructing or construction activities,” “safety-related SSCs,” and “security-related SSCs.” The NRC has added these definitions in response to public comments that recommended that the NRC reconsider the proposed requirements for licensees or other entities who will build new nuclear power plants. The NRC defined these terms to clarify the point in the construction process at which an FFD program for construction is required, the physical location where the FFD program for construction must be implemented, and to specify the individuals who are subject an FFD program for construction in terms of the duties they will perform.

The former rule in § 26.2(c) imposed FFD requirements on construction permit holders “with a plant under active construction” but did not define that term. The proposed rule in

§ 26.3(e) would have required an FFD program for construction following NRC authorization to construct. However, the NRC recognizes that there may be a period of time that elapses between the authorization to construct and the commencement of specific construction activities that have the potential to affect public health and safety and the common defense and security when the nuclear power plant begins operations. Therefore, the NRC has added a definition of constructing and construction activities to clarify that an FFD program for construction is not required until a licensee or other entity begins "fabricating, erecting, integrating, and testing the nuclear power plant SSCs that are required by the Commission's rules and regulations to be described in the site safety analysis report, preliminary or final safety analysis report, or physical security or safeguards contingency plans, and the installation of their foundations, including the placement of concrete."

In addition, this definition also specifies that the FFD program for construction applies only to construction activities that are performed at the location where the new plant will be constructed and operated. The NRC added this phrase to the definition of construction activities to clarify that any fabrication, integration, or testing of safety- or security-related SSCs that is not performed within or near the licensee's or other entity's owner-controlled area in which the new plant will be operated would not be subject to Subpart K. For example, fabricating, integrating, and testing safety- or security-related SSCs at a vendor's or manufacturer's facility that is located in another city or state or outside of the U.S. would not be subject to Subpart K, whereas producing the concrete to be used for the foundation of the reactor building in a facility located on the construction site would be subject to Subpart K (although the construction of the cement mixing facility would not). The NRC anticipates that the focus of the Subpart K program on construction activities involving safety- and security-related SSCs at the location where the new plant will be constructed and operated will lead licensees and other entities to ensure that the program covers all those individuals who perform

construction activities within the footprint of the new power reactor (e.g., the exterior boundary of the reactor building once it is completed) as well as the nearby areas where safety- and security-related SSCs will be installed and operate when the plant begins operations.

The former rule and the proposed rule also did not specify the individuals who would be subject to an FFD program for construction. The NRC recognizes that there will be other construction work performed at the location where a new plant will be constructed and operated that will not have the potential to affect public health and safety and the common defense and security when the nuclear power plant begins operations, such as constructing a building that will be used only for training or administration purposes. The NRC does not intend that individuals who are performing these other construction activities must be subject to the FFD program. Therefore, the final rule also includes definitions of safety- and security-related SSCs to clarify that only those individuals who are constructing (i.e., fabricating, erecting, integrating, testing, and installing foundations) these specific SSCs must be subject to a Subpart K program. Thus, as one example of a safety-related SSC, the rule requires individuals who are constructing the containment structure that surrounds the reactor to be subject to an FFD program because the containment is relied on to mitigate the consequences of accidents that could result in potential offsite exposure. Similarly, individuals who are constructing safety-related SSCs, such as the central and secondary alarm stations, physical barriers, communications systems, guard towers, surveillance and detection systems, or installing locks and illumination systems, that will be necessary to implement the physical security and safeguards contingency plans that are required under 10 CFR Part 73 also are subject to an FFD program for construction.

The development of the revised requirements contained in Subpart K (described in Sections V and VI of this document) compelled the NRC to define these terms in the final rule. Adding definitions of these terms satisfies Goal 6 of this rulemaking as it relates to improving

clarity in the language of the rule.

The final rule also adds many terms related to other revisions to the former rule. Specifically, the final rule adds “analytical run” for use in establishing amended performance testing requirements for licensee testing facilities in § 26.137 [Quality assurance and quality control]. For consistency with the use of the term in the related regulations of other Federal agencies, the term “donor” replaces the former terms that are used to refer to an individual from whom a specimen is collected for drug or alcohol testing. The new term “nominal” refers to the leeway in the time periods within which certain requirements must be met, such as the requirement for annual FFD refresher training in § 26.29(c)(2). The term “other entity” refers to organizations who are 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 § 26.3 [Scope]. The terms “formula quantity” and “strategic special nuclear material” (SSNM) have been defined consistently with the definitions of the same terms in 10 CFR 70.4. The term “subversion and subvert the testing process” clarifies the language of provisions related to urine specimen validity testing, as discussed with respect to § 26.31(d)(3)(i), and sanctions in § 26.75(b) that are imposed on individuals who are subject to Part 26.

Section 26.5 of the final rule also retains and amends a number of other definitions formerly contained in § 26.3 and Section 1.2 in Appendix A to Part 26, as described in the following paragaphs.

The rule revises the former 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 is consistent with the same definition in the HHS Guidelines.

The final rule simplifies the former definition of “blood alcohol concentration (BAC)” by deleting references to the instruments that licensees and other entities are permitted to use for alcohol testing. The text of § 26.91 [Acceptable devices for conducting initial and confirmatory

tests for alcohol and methods of use] specifies acceptable devices for alcohol testing under the final rule.

The final rule revises the definition of “category IA material” to conform with the former definition contained in 10 CFR 74.4.

The final rule expands the definition of “chain of custody” to indicate that the terms “chain of custody” and “custody and control” are synonymous.

The NRC has modified the definition of “collection site” in the final rule 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 in Section VI of this document with respect to § 26.83(a).

The final rule replaces 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 no longer includes the qualifications required for collectors because they are specified in § 26.85 [Collector qualifications and responsibilities].

The final rule adds the term “contractor/vendor (C/V),” combining the definitions of “contractor” and “vendor” in the former rule, because the final rule does not distinguish between the two types of entities.

The final rule updates 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 final rule simplifies the definition of “licensee testing facility” by eliminating the reference to collecting specimens for alcohol testing in the former definition, because alcohol testing typically occurs at a collection site rather than at the licensee testing facility. Also, with respect to the proposed rule, the NRC has clarified this definition in the final

rule to be consistent with the inclusion of specimen validity testing at licensee testing facilities.

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

Section 26.7 Interpretations.

Section 26.7 in the final rule retains former § 26.4 [Interpretations] but moves the qualifying phrase, “other than a written interpretation by the General Counsel,” to the end of the sentence to improve its clarity. The NRC has made this change in keeping with the Commission’s commitment to using plain language in its regulations and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the final rule.

Section 26.8 Information collection requirements: OMB approval.

Section 26.8 in the final rule amends former § 26.8 [Information collection requirements: OMB approval] to reflect the modified sections of the final rule in which recordkeeping requirements are incorporated.

Section 26.9 Specific exemptions.

Section 26.9 in the final rule revises former § 26.6 [Exemptions] to include the citation of 10 CFR 50.12 and 70.17. The NRC has made this change in the final rule to ensure consistency between Part 26 and these related requirements.

Section 26.11 Communications.

New § 26.11 in the final rule improves consistency with similar sections in other parts of 10 CFR and ensures that communications with the NRC are addressed and, therefore, processed properly.

Subpart B – Program Elements

Throughout Subpart B, the final rule makes minor clarifications to the proposed rule because of public comment, to make conforming changes, and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule also makes more substantive changes to the proposed rule in this subpart because of public comment or to improve clarity in the organization and language of the rule. The substantive changes in this subpart can be found in §§ 26.21; 26.27(b)(3), (c)(1), (c)(2)(ii), (c)(3), and (c)(3)(ii); 26.29(c)(2); 26.31(d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(v), (d)(3)(i), and (d)(3)(iii); 26.35(b); 26.37(a), (b)(5) and (d); 26.39(c) and (e); and 26.41(a). These changes are discussed in detail below. However, other than the changes mentioned above, the final rule adopts the provisions of this subpart as proposed, without change.

Section 26.21 Fitness-for-duty program.

The final rule modifies the proposed rule's text in this section to specify which entities and individuals are subject to the requirements of this subpart. This section requires that the

licensees and other entities specified in § 26.3(a) through (c) must establish, implement, and maintain FFD programs that, at a minimum, comprise the program elements contained in this subpart. This new statement serves as an introduction to the remaining text of the final rule and eliminates the need for the phrase " [licensees and other entities] who are subject to this subpart" (or a derivation of this phrase) from several provisions in this subpart. These changes are consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has also added a sentence to this section to specify which individuals are subject to FFD programs. The sentence in the final rule includes cross-references to provisions in § 26.4 [FFD program applicability to categories of individuals], which eliminates the need for the phrase "[individuals] who are subject to this part" (or a derivation of this phrase) from several provisions in this subpart. This change is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The third sentence of the section of the final rule is based on former § 26.23(b). This provision retains permission for licensees and other entities to rely upon the FFD program or program elements of a C/V to meet the requirements of this part, if the FFD program or program element of a C/V meets the applicable requirements of this part. The other requirements contained in former § 26.23 [Contractors and vendors] are discussed with respect to § 26.23 [Performance objectives].

Section 26.23 Performance objectives.

Section 26.23 amends former § 26.10 [General performance objectives] as described in the following paragraphs.

The final rule divides the performance objectives contained in § 26.10(a) into two provisions (§ 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.

Section 26.23(a) of the final rule requires that FFD programs provide 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. 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 since September 11, 2001. These are the same individuals who are subject to the final rule. Because these individuals have unimpeded access to sensitive information and safety equipment and systems, their trustworthiness and reliability are essential. This level of emphasis is necessary 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. Substance abuse by these individuals presents an unacceptable risk to public health and safety and the common defense and security in several ways.

First, by increasing an individual's vulnerability to coercion, substance abuse increases the likelihood that such individuals may pose an insider threat. Under 10 CFR 73.1 [Purpose and scope], 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 this 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 former rule provided 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 changes to the former rule provide further assurance that individuals who are subject to the rule are trustworthy and reliable. Changes to strengthen the effectiveness of the final rule in assuring individuals' trustworthiness and reliability include, but are not limited to, the following:

(1) Adding requirements for specimen validity testing to identify individuals who are willing to attempt to subvert the testing process, and 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 any individual who attempts to subvert the drug and alcohol testing process.

The NRC believes that implementation of these provisions of the final rule, in addition to related measures the agency has taken in the post-September 11, 2001, threat environment, provides an increased level of requirements appropriate for the new threat environment, as well as reasonable assurance that individuals who are subject to the rule are trustworthy and reliable.

Section 26.23(b) of the final rule retains the performance objective of providing reasonable assurance that personnel are fit for duty, which appeared in former § 26.10(a). The use of the term “reasonable” to describe the level of assurance required by the rule reflects the NRC’s awareness that many different factors may affect an individual’s fitness at any particular moment in time. 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 do not pose a significant risk to public health and safety.

As mentioned above, the level of requirements associated with achieving reasonable assurance of trustworthiness and reliability is greater than that associated with achieving reasonable assurance that individuals are not impaired. Another example of this relates to the sanctions that the final rule requires licensees and other entities to impose on individuals who demonstrate questionable trustworthiness and reliability compared to the management actions licensees are 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 final rule (under § 26.75(b) and 26.75(c),

respectively) requires the licensee or other entity to terminate the individual's authorization. Terminating the individual's authorization is necessary to provide reasonable assurance that the individual could pose no further risk to public health and safety or the common defense and security. In contrast, the final rule does 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 or 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 final (and former) rule (under § 26.77(b)(3) and former § 26.27(b)(1), respectively) require the licensee or other entity to take action to prevent the individual from performing the 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 `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 after the headache is resolved.

Another difference between the performance objectives of providing "reasonable" assurance of trustworthiness and reliability and "reasonable" assurance that the individuals who are subject to the final 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 § 26.75(b) but would take less severe 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 § 26.77(b)(3).

Section 26.23(c) of the final rule retains the performance objective in former § 26.10(b) to "provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of this part." However, the final rule replaces the phrase "perform activities within the scope of this part" with the phrase "perform the duties that require them to be subject to the FFD program." The final rule requires that certain individuals must be subject to an FFD program based on their duties. These duties include performing activities, such as measuring, guarding, or transporting Category IA material. They also include 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 before the MRO reviews those results. Therefore, the phrase "perform the duties that require them to be subject to the FFD program" is more accurate. Replacing the former phrase with the more accurate phrase is consistent with Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

Section 26.23(d) of the final rule amends former § 26.10(c) to require that FFD programs must provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol. The final rule revises the former 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 final rule replaces “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 are proscribed. This revision clarifies 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. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

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

Section 26.23(e) of the final rule adds a provision 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 new performance objective, consistent with Goal 2 of this rulemaking 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 of worker fatigue, specifies the objective of the requirements concerning worker fatigue that the NRC has added to the final rule. Worker fatigue cannot be measured or controlled with precision. Also, licensees and other entities do not have direct control over all

matters that may influence worker fatigue. Therefore, § 26.23(e) establishes a "reasonable assurance" criterion for the 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 related to 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, § 26.23(e) establishes a performance objective of 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 performance objective permits 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 [Reserved]

The final rule has amended and moved the requirements from proposed § 26.25 [Individuals subject to the fitness-for-duty program] to § 26.4 [FFD program applicability to categories of individuals] of the final rule. This change is discussed in detail in this document with regard to § 26.4.

Section 26.27 Written policy and procedures.

Section 26.27 of the final rule reorganizes and amends former § 26.20 [Written policy and procedures. The final rule divides into separate paragraphs the requirements related to the FFD policy and FFD program procedures that are intermixed within the former section. This organizational change makes the requirements related to the FFD policy and procedures easier to locate within this section, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(a) of the final rule amends the first paragraph of former § 26.20. The former provision required 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 final rule replaces the term "licensee" in the former rule with the phrase "licensees and other entities" because entities other than licensees are subject to this requirement, as discussed with respect to § 26.3 [Scope]. The final rule adds the term "maintain" to the former 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 final rule replaces "specific" with the term "applicable" in the final sentence because all the requirements in Part 26 do not apply to all the licensees and other entities who are subject to the rule, as discussed with respect to § 26.3 [Scope]. The final rule also eliminates "designed to" from this sentence because it is unnecessary. The NRC has moved the records retention requirements contained in the second sentence of the former provision to § 26.713(d) in Subpart N [Recordkeeping and Reporting Requirements] of the final rule. Subpart N groups together the recordkeeping and reporting requirements that are interspersed throughout the

former rule. The NRC has made these changes to the organization and language of former § 26.20 to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(b) of the final rule amends former § 26.20(a). The former provision established requirements for the written FFD policy, and the final rule expands the list of topics that the FFD policy must address as a result of discussions with stakeholders during the public meetings mentioned in Section I.D. Stakeholders noted that the list of topics in the former 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 final rule adds topics to the policy content requirements in former § 26.20(a) to ensure that FFD policies will be complete. The NRC has made this change to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to Part 26.

Section 26.27(b) of the final rule also adds 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 former nor final 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 positive, adulterated, or substituted 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 this final rule, the written FFD policy continues to be the primary means by which a licensee or other entity communicates 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 final rule adds 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. The NRC has made this change to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to Part 26.

The final rule also adds 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. The NRC has added these examples to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(b)(1) amends the second sentence of former § 26.20(a). Former § 26.20(a) required that "the policy must address the use of illegal drugs and abuse of legal drugs (e.g., alcohol, prescription and over-the-counter drugs)." Section 26.27(b)(1) of the final rule expands 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 § 26.27(b)(i); the abuse of legal drugs and alcohol in § 26.27(b)(ii); and the misuse of prescription and over-the-counter drugs in § 26.27(b)(iii). The final rule replaces the phrase "must address" in the former sentence with the phrase "must describe the consequences of." The updated phrase clarifies 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. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule adds § 26.27(b)(2) that requires the FFD policy to state the time period specified by the licensee or other entity within which individuals must report to the collection site after being notified that they have been selected for random testing. The provision does not establish a time limit because there are a variety of circumstances among the different

licensees and other 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 is 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. Furthermore, 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 because of metabolism. As a result, 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 requirement to establish a time limit within which individuals must report for random testing after notification meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs. The final rule also requires 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. The NRC has made this change to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to Part 26.

Section 26.27(b)(3) adds a requirement that the FFD policy inform individuals of the consequences of refusing to be tested and attempting to subvert the testing process. With respect to the proposed rule, the final rule clarifies that the written policy statement must also describe the actions that constitute a refusal to provide a specimen for testing. This change, in response to a public comment, clarifies the intent of the provision, consistent with Goal 6 of the rulemaking to improve clarity in the language and organization of the rule. This provision

ensures that persons who are subject to the rule are aware of § 26.75(b), which requires licensees and other entities to impose the sanction of permanent denial of authorization for these actions. Section 26.27(b)(3) protects 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 to the final rule meets Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to Part 26.

Section 26.27(b)(4)(i) amends former § 26.20(a)(1). Former § 26.20(a)(1) required the FFD policy to prohibit the consumption of alcohol within an abstinence period of at least 5 hours preceding "any scheduled working tour." The final rule replaces 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 former rule at the public meetings mentioned in Section I.D. The stakeholders commented that the former phrase lacked 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 revised language of the final rule clarifies 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 § 26.27(c)(3). The NRC has made this final change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(b)(4)(ii) retains former § 26.20(a)(2) without change.

The NRC has added § 26.27(b)(5) to the final rule to require that the FFD policy inform

individuals that abstinence from alcohol during the 5 hours preceding any scheduled tour of duty 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 § 26.103 [Determining a confirmed positive test result for alcohol] preceding a scheduled tour of duty, depending on the amount of alcohol and food that the individual consumed before the abstinence period began, body weight, and other factors. By ensuring that individuals who are subject to this part are aware that the required 5-hour abstinence period may be insufficient to ensure they have a BAC below the cutoff levels in this part when arriving at the licensee's or other entity's facility, this provision to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to alcohol testing under Part 26.

Section 26.27(b)(6) amends the last sentence of former § 26.20(a). That sentence required 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 final rule adds 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 reassigned to 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 final rule requires 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 rights (including due

process) of individuals who are subject to the policy. The addition of this requirement also increases the internal consistency of the rule because other portions of the final rule establish requirements related to using prescription and over-the-counter medications. For example, § 26.29(a)(6) requires FFD training to address use of prescription and over-the-counter medication. Also, § 26.185(j)(2) requires the MRO to determine whether a positive confirmatory drug test result that results from using a prescription or over-the-counter medication represents substance abuse. Therefore, the requirement for the FFD policy to address the use of prescription and over-the-counter medications that could cause impairment at work also meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(b)(7) amends former § 26.20(b). Former § 26.20(b) required 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 duties. Section 26.27(b)(7) of the final rule adds 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 that 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 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 because of sleepiness (National Sleep Foundation, 2000). Section 26.27(b)(7) ensures that individuals are aware of the services that are available for diagnosing and treating sleep disorders that can adversely affect their job performance. The NRC has made this change to meet Goal 2 of this rulemaking 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 final rule replaces the phrase "adversely affect the performance of activities within the scope of this part" in the former provision with the phrase "could adversely affect an individual's ability to safely and competently perform the duties that require an individual to be subject to this part" for the reasons discussed with respect to § 26.23(c).

Section 26.27(b)(8) retains the requirement in former § 26.20(d) that the FFD policy must specify the consequences of violating the policy. The NRC has moved the former requirements that were related to the procedures that the licensee or other entity would implement if an individual violates the FFD policy to § 26.27(c) of the final rule, which addresses FFD program procedures, for organizational clarity.

Section 26.27(b)(9) adds a requirement that licensees' and other entities' FFD policies must describe the individual's responsibility to report legal actions, as defined in § 26.5 [Definitions]. The new requirement to report legal actions is discussed with respect to § 26.61 [Self-disclosure and employment history]. The final rule requires the FFD policy to address the reporting of legal actions to ensure that individuals are aware of this and are not at risk of sanctions for failing to report any legal actions. Thus, the NRC has made this change to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to the policy.

Section 26.27(b)(10) adds a requirement for the FFD policy to describe the responsibilities of managers, supervisors, and escorts to report FFD concerns. The former rule implied that managers and supervisors have the responsibility to report FFD concerns in § 26.22(a)(5), which required managers and supervisors to be trained in procedures "for initiating appropriate corrective action." Similarly, the last phrase of former § 26.22(b) required that escorts be trained in procedures "for reporting problems to supervisory or security

personnel" and, therefore, also implied that escorts have a reporting responsibility. However, the former rule did not explicitly state that the FFD policy must convey this requirement. Therefore, the final rule adds § 26.27(b)(10) to enhance the internal consistency of the rule. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(b)(11) adds a requirement for the FFD policy to state that individuals who are subject to the rule must report FFD concerns, consistent with § 26.33 [Behavioral observation]. Section 26.33 requires 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. Section 26.29 [Training] requires individuals to be trained in behavioral observation. The agency has added these requirements to enhance the effectiveness of Part 26 by ensuring the early detection of individuals who are not fit to perform the duties that require them to be subject to this part. This is one of the performance objectives that FFD programs must meet, as discussed with respect to § 26.23(c). This provision also improves consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56 [Personnel access authorization requirements for nuclear power plants] as supplemented by orders to nuclear power plant licensees dated January 7, 2003, as discussed in Section IV.B of this document. The specific requirement in § 26.27(b)(11) for licensees' and other entities' FFD policies to state that individuals must report FFD concerns is 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 to protect the rights (including due process) of individuals who are subject to the policy.

Section 26.27(c) of the final rule combines the requirements related to procedures

contained in former § 26.20(c) through (e), and adds other requirements, as described in the following paragraphs.

Section 26.27(c)(1) retains the requirements in former § 26.20(c). The NRC has replaced the phrase in the proposed rule "privacy and due process rights of an individual who provides a specimen" with the phrase "privacy and other rights (including due process) of an individual who provides a specimen" in the final rule. The NRC has made this change in response to a public comment that stated the proposed phrase may be interpreted to limit individuals' protected rights to due process. This phrase clarifies the requirement for "protecting the employee" contained in former § 26.20(c). For example, individuals' privacy rights under the final 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. Other examples of individuals' rights under the final 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 positive, adulterated, or substituted test result. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(c)(2)(i) and (c)(2)(ii) divides former § 26.20(d) into separate paragraphs that address different topics. Section 26.27(c)(2)(i) retains the former requirement that licensees and other entities must 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. Like the former provision, § 26.27(c)(2)(ii) requires 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 prework

abstinence period, or while on duty, as determined by a test that measures BAC. With respect to the proposed rule, the final rule also adds the phrase “or consumed any alcohol during the mandatory prework abstinence period” to clarify the prohibition against any alcohol consumption, not only excess consumption, during the pre-work abstinence period. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(c)(2)(iii) and (c)(2)(iv) adds requirements that licensees and other entities must prepare written procedures for implementing the FFD program that describe immediate and followup actions for attempted subversion of the testing process. Section 26.27(c)(2)(iii) requires 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. Section 26.27(c)(2)(iv) requires procedures to address the actions to be taken if an individual has refused to provide a specimen for testing. The final rule adds these provisions for consistency with § 26.75(b). Section 26.75(b) requires licensees and other entities to terminate an individual’s authorization and, thereafter, permanently deny authorization to any individual who has committed or attempted any 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 § 26.31(c). Adding the requirements for procedures to address these circumstances meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(c)(2)(v) adds a requirement that the written procedures must describe immediate and followup actions for individuals who have had drug- or alcohol-related legal actions taken against them, as defined in § 26.5. This provision supports related provisions in § 26.69(d). Section 26.69(d), in general, requires 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 duties that require them to be subject to this part. Adding the requirement for procedures to address these circumstances ensures the internal consistency of the final rule and meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has reorganized § 26.27(c)(3) of the final rule, with respect to the proposed rule, to clarify which provisions apply to "emergencies" and which apply to "unscheduled working tours." The NRC received a public comment that suggested the term "emergency" may be too limiting. However, the NRC believes the term "emergency" accurately reflects NRC's intent and has retained this term in the final rule. Section 26.27(c)(3) amends former § 26.20(e). The provision requires 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 final rule retains and modifies the other requirements of former § 26.20(e), as described in the following paragraphs.

Section 26.27(c)(3)(i) retains former § 26.20(e)(1). The provision 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. The final rule adds the requirement 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 because the NRC recognizes that conditions other than the consumption of alcohol 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]). The NRC received a comment suggesting that individuals who are called in should only be required to report if they are not fit for duty or have consumed alcohol during the pre-duty abstinence period. The NRC believes that this alternative would be less protective of public health and safety, as an

affirmative obligation to provide a statement may dissuade individuals who would be tempted to remain silent. Requiring individuals to report other conditions that may cause them to be impaired when called in under § 26.27(c)(3)(i), strengthens 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 § 26.27(c)(3)(iii). Therefore, the NRC has adopted the proposed provision as final. The NRC has made these changes to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.27(c)(3)(ii) specifies the procedures to follow if the individual has consumed alcohol in the pre-duty abstinence period and is called in for an unscheduled working tour, including an unscheduled working tour to respond to an emergency. Section 26.27(c)(3)(ii)(A) retains former § 26.20(e)(2). The provision requires that an individual who reports that he or she has used alcohol and is called in must be subject to a determination of fitness by breath analysis. The NRC has added a new § 26.27(c)(3)(ii)(B) to the final rule to permit the licensee or other entity to assign the individual to duties that require him or her to be subject to this part, if the results of the determination of fitness indicate that the individual is fit to safely and competently perform his or her duties. The NRC has also added a new § 26.27(c)(3)(ii)(C) to the final rule to prohibit the licensee or other entity from assigning the individual to duties that require him or her to be subject to this part, if the individual is not required to respond to an emergency and the results of the determination of fitness indicate that the individual may be impaired. The NRC has also added § 26.27(c)(3)(ii)(D) that retains a portion of former § 26.20(e)(3). The provision requires the procedures to state that 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. This provision also retains and modifies a portion of former § 26.20(c)(3). It states

that if the determination of fitness indicates that an individual who has been called in for an unscheduled working tour to respond to an emergency may be impaired, the procedure must require the establishment of controls and conditions under which the individual who has been called in can perform work if necessary.

The NRC has added § 26.27(c)(3)(ii)(E) to the final rule to clarify that licensees and other entities may not impose sanctions if an individual is called in for an unscheduled working tour for having consumed alcohol during the preduty abstinence period specified in the FFD policy. This change ensures 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 believes that sanctions for the consumption of alcohol in these circumstances would be inappropriate because the individual would have been unaware that he or she would be called in to work. The revision is also consistent with the original intent of the rule. Therefore, the NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(c)(4) adds a requirement that FFD procedures must describe the process to be followed when another individual's behavior raises an FFD concern and the process for reporting the concern. As discussed with respect to § 26.27(b)(11), this provision is consistent with § 26.33 [Behavioral Observation], which establishes a requirement that all individuals must perform behavioral observation and report any FFD concerns. This provision is also consistent with § 26.29 [Training], which requires individuals to be trained to perform behavioral observation. The NRC has added this requirement to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 4 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 26.27(d) of the final rule retains the requirements of former § 26.20(f) without changes.

Section 26.29 Training.

Section 26.29 of the final rule combines and amends former § 26.21 [Policy communications and awareness training] and § 26.22 [Training of supervisors and escorts]. This section clarifies that all individuals subject to this subpart must receive the same scope of training, to include, for example, behavioral observation, whereas former § 26.22 required that only supervisors and escorts must receive behavioral observation training. Increasing the number of individuals who are trained in behavioral observation enhances the effectiveness of FFD programs by increasing the likelihood of detecting potential impairment, consistent with Goal 3 of this rulemaking.

Section 26.29(a) of the final rule combines the training topics listed in former §§ 26.21(a)(1) through (a)(5), 26.22(a)(1) through (a)(5), and 26.22(b). The agency has rewritten the required training topics in terms of knowledge and abilities (KAs) to be consistent with terminology used by licensees and other entities in other required training programs. This change meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.29(a)(1) combines former § 26.21(a)(1) with the latter portion of former § 26.21(a)(5). Consistent with the former training requirements, the provision requires licensees and other entities to ensure that individuals who are subject to this subpart 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.

Section 26.29(a)(2) retains the requirement in former § 26.22(a)(1) that licensees and other entities 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.

Section 26.29(a)(3) amends the terminology used in former § 26.22(a)(2). Former § 26.22(a)(2) required FFD training to address the roles and responsibilities of others, such as the personnel, medical, and employee assistance program (EAP) staffs. The final rule replaces the references to the "personnel" function and "medical" staff in former § 26.22(a)(2) with "human resources" and "FFD" staff, respectively. The final rule also moves the reference to the MRO into this section from former § 26.21(a)(3). These updates to the terminology in this section are consistent with other terms used throughout the final rule to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.29(a)(4) and (a)(5) amends former § 26.21(a)(4) and (a)(2), respectively, by changing some of the language used in the former provisions. Former § 26.21(a)(4) required FFD training to inform individuals who are subject to the rule of any EAPs that are available to them. The final rule eliminates the reference to EAPs "provided by the licensee" in the former provision and amends it as "EAP services available to the individual" because other entities are also subject to this requirement under the final rule. Section 26.29(a)(5) amends former § 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. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.29(a)(6) retains the portion of former § 26.21(a)(3) that required licensees to ensure that individuals understand the effects of prescription and over-the-counter drugs and dietary factors on job performance. The final rule adds a requirement for FFD training to

address the effects of alcohol, 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 NRC has moved the requirement in the last sentence of former § 26.20(a) to § 26.27(b)(6) of the final rule because that section addresses FFD policy requirements. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.29(a)(7) retains the portion of former § 26.21(a)(3) that required 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.

Section 26.29(a)(8) and (a)(9) of the final rule retains the requirements in former § 26.22(a)(3) and (a)(4), respectively, without changes.

Section 26.29(a)(10) amends former § 26.22(a)(5). The provision retains the former 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, including referral to the EAP. The final rule adds a requirement for FFD training to ensure that individuals understand their responsibility to report FFD concerns to the person(s) who are designated to receive such reports in FFD program procedures. This change is consistent with § 26.33 [Behavioral Observation], which requires individuals to perform behavioral observation and report any FFD concerns, as discussed with respect to § 26.27(b)(11). The change is also consistent with § 26.27(c)(4), which requires procedures for implementing the requirement. The NRC has added this group of interrelated requirements to meet Goal 3 of this rulemaking

to improve the effectiveness and efficiency of FFD programs and Goal 4 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 26.29(b) of the final rule adds a requirement that individuals must demonstrate attainment of the KAs specified in § 26.29(a) by passing a comprehensive examination. The NRC has added this requirement because in several instances since Part 26 was first promulgated, 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 could not be expected to comply with the requirements of the policy. Therefore, the final rule requires individuals to demonstrate their attainment of the KAs listed in § 26.29(a) to ensure that the FFD training has been effective. The final rule requires remedial training for those who fail to achieve a passing score of 80 percent on the examination. Section 26.29(b) also requires the examination to include at least one question for each KA. These requirements are 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. Establishing a method to ensure that individuals understand the requirements with which they must comply meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

The provision also permits 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 meets the portion of Goal 3 of this rulemaking to improve the efficiency of FFD programs. The permission also meets Goal 5 to improve Part 26 by eliminating or modifying unnecessary requirements

through providing flexibility in the methods that licensees and other entities may use to administer the required examination.

Section 26.29(c) of the final rule combines and amends the portions of former §§ 26.21(b) and 26.22(c) that required FFD training for individuals who are subject to this section before they are permitted to perform duties that require them to be subject to this part.

Section 26.29(c)(1) requires that all personnel who are subject to this section must complete FFD training before the licensee or other entity grants initial authorization to the individual, as defined in § 26.55 [Initial authorization]. The final rule also requires 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 § 26.57 [Authorization update] and § 26.59 [Authorization reinstatement], respectively. The provision also eliminates the requirement in former § 26.22(c) to upgrade training for newly assigned supervisors within 3 months of a supervisory assignment because all personnel will receive the same scope of training and be required to complete the training before a licensee or other entity grants authorization to any individual. These changes are consistent with the requirements related to granting and maintaining authorization that are established in Subpart C [Granting and Maintaining Authorization] of the final rule, as discussed in this document with respect to that subpart. The changes also meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.29(c)(2) retains and combines the requirements for annual refresher training in former §§ 26.21(b) and 26.22(c). Former § 26.21(b) addressed individuals who are subject to this part and former § 26.22(c) addressed supervisors and escorts. The final rule combines the former requirements because all personnel receive the same scope of training under the final rule. The final rule specifies that individuals must complete the refresher training every 12 months, or more frequently when the need is indicated. With respect to the proposed rule, the

final rule gives some examples of situations that indicate a need to conduct the refresher training more frequently that every 12 months, but this list is not inclusive of all situations that may indicate this need. Adding these examples clarifies the NRC's intent and meets Goal 6 of the rulemaking to clarify the language of the rule. The final provision permits individuals who pass a comprehensive annual examination that demonstrates their continued understanding of the FFD program requirements to be excused from the refresher training that the provision otherwise requires. The examination is necessary to meet the examination requirements specified in § 26.29(b) [Comprehensive examination]. Individuals who do not pass must undergo remedial training. Permitting individuals to pass a comprehensive examination rather than take refresher training each year ensures that they are retaining their FFD KAs while reducing some costs associated with meeting the annual refresher training requirement. Therefore, this change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.29(c)(3) permits 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 § 26.29(b) [Comprehensive examination] that permits licensees and other entities to use various media to administer the comprehensive examination. The requirements for a licensee or other entity to monitor the completion of training and provide access to an instructor or subject matter expert ensures that individuals who are trained using different media achieve the same understanding as persons who are trained in a classroom setting with an instructor present. This flexibility may reduce the costs associated with presenting initial and refresher training only in a classroom setting. Therefore, this change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

To meet the annual refresher training requirement for individuals, § 26.29(d) of the final

rule permits licensees and other entities to accept the training of individuals who have been subject to another training program that meets the requirements of this section. Licensees and other entities are also permitted to accept a passing result from a comprehensive examination that was administered by another training program that meets the requirements of this section in lieu of refresher training, if the examination meets the requirements of § 26.29(b) [Comprehensive examination]. This requirement meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.31 Drug and alcohol testing.

Section 26.31 of the final rule renames former § 26.24 [Chemical and alcohol testing]. The final rule, in general, replaces the former term “chemical testing” with “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. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(a) [General] of the final rule retains but updates the language in former § 26.24(a) to be consistent with the new terminology used throughout the rule as discussed in § 26.5 [Definitions]. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.31(b) [Assuring the honesty and integrity of FFD program personnel] of the final rule amends former Section 2.3 in Appendix A to Part 26. Other than making minor clarifications to the rule text as explained below, the NRC has adopted the requirements of paragraph (b) of this section as proposed, without change.

Section 26.31(b)(1) amends the first paragraph of former Section 2.3 in Appendix A to Part 26. This paragraph required licensees to carefully select and monitor persons responsible

for administering the testing program to ensure that they meet the highest standards of honesty and integrity. The final rule replaces the former list of individuals who are subject to this requirement with a cross-reference to § 26.4(g) of the final rule, which specifies in detail the FFD program personnel who must be subject to the FFD program. This cross-reference avoids repeating the list of personnel in this provision.

The provision also adds 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 are not limited to, a substance abuse problem or financial problems. Therefore, the final rule adds 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 NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.31(b)(1)(i) amends former Section 2.3(2) in Appendix A to Part 26 in response to implementation questions regarding the former requirements. The provision clarifies 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 final rule retains the term “appropriate” in the former rule for two reasons. First, it indicates that FFD program personnel who are employed by entities who are subject to the rule but are not nuclear power plants, may meet the requirements through investigations, checks, and evaluations that provide the information needed to determine the honesty and integrity of FFD program personnel, but the

investigations, checks, and evaluations may differ from those required under nuclear power plant access authorization programs. In addition, the final rule retains 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” is 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. The NRC has made these changes to meet the portion of Goal 6 of this rulemaking that pertains to improving clarity in the language of the rule.

The NRC has relaxed the requirement in former Section 2.3(2) in Appendix A to Part 26 for appropriate background checks and psychological evaluations to be conducted at least once every 3 years to require that credit and criminal history checks and updated psychological assessments be conducted nominally every 5 years. The final rule relaxes the former 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 final rule retains the former requirement for updated background checks and psychological assessments, but reduces the required frequency of these updates from every 3 years to every 5 years under the final rule. The NRC has made this change to meet Goal 5 of this rulemaking to improve Part 26 by

eliminating or modifying unnecessary requirements. In addition, the frequency for these updates increases 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.

Section 26.31(b)(1)(ii) amends and clarifies former Section 2.3(1) in Appendix A to Part 26 in response to the many implementation questions that have arisen after the regulation was published. The former rule prohibited individuals who have a personal relationship with the individual being tested (i.e., a donor), such as the donor's "supervisors, coworkers, and relatives," from performing any "collection, assessment, or evaluation procedures" involving the individual being tested. The NRC included the restriction on "supervisors, coworkers, and relatives" in the former rule to provide examples of the "personal relationships" referenced in the introductory paragraph of former Section 2.3 in Appendix A to Part 26. Some licensees have misinterpreted the restriction on coworkers in the former rule 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, many individuals employed by the same corporation will not have personal relationships with FFD program personnel, specifically, or with other individuals who are subject to testing, in general. Therefore, in § 26.31(b)(1)(ii), the phrase "in the same work group" clarifies 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 would be considered "coworkers in the same work group" to whom the restriction applies. In addition, the section adds a reference to determinations of fitness (discussed with respect to § 26.189 [Determination of fitness]) to provide a clarifying example of the assessment and evaluation procedures that FFD program personnel are prohibited from performing if the FFD program staff member has a personal relationship with the subject individual. The NRC has made these changes to meet Goal 6 of this rulemaking to

improve clarity in the organization and language of the rule.

Section 26.31(b)(1)(iii) relaxes the prohibition on individuals who have “personal relationships” with the donor from performing specimen collection procedures in former Section 2.3(1) in Appendix A to Part 26. The NRC acknowledges that the former restriction imposed an unnecessary burden when the objective of ensuring the integrity of specimen collections in these circumstances could be achieved by other means. Therefore, in § 26.31(b)(1)(iii), individuals who have a personal relationship with a donor are permitted to collect specimens, if 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 monitors the collection and preparation of the specimens for shipping. The section also provides 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. By permitting monitored collections in these circumstances while continuing to assure the integrity of specimen collections from FFD program personnel, this provision meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. The final rule retains the prohibition for individuals who have personal relationships with the donor from performing assessment and evaluation procedures because monitoring of these activities by qualified personnel is not feasible.

If a directly observed collection is required, § 26.31(b)(1)(iv) of the final rule adds a prohibition for an individual who has a personal relationship with the donor from acting as a urine collector or observer. This prohibition is necessary to minimize embarrassment to the donor (and the collector) during a directly observed collection. The NRC has added this provision to meet Goal 7 of this rulemaking, relating to protecting the privacy rights of individuals who are subject to Part 26.

Section 26.31(b)(1)(v) amends former 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 § 26.31(b)(1)(v), a "facility" includes, but is not limited to, a licensee's or other entity's corporate offices and any medical facilities that the licensee or other entity operates. The NRC has added this requirement 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 final rule limits 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 requirement for behavioral observation of MROs to those instances in which the MRO is working on site at a licensee's or other entity's facility is adequate to ensure the continuing honesty and integrity of these MROs because MROs who work off site would not interact 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. The final rule continues to require all MROs to be subject to the other FFD program elements that are required in this subpart. These elements include drug and alcohol testing and regular psychological assessments and background investigations, which permit licensees and other entities to monitor the honesty and integrity of off-site MROs. The NRC has added this relaxation to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

A new § 26.31(b)(2) provides another relaxation from the former rule related to collecting specimens from FFD program personnel. The provision permits 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 § 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 is adequate to meet the goal of ensuring their continuing honesty and integrity. Therefore, the NRC has added this provision to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.31(c) [Conditions for testing] replaces former § 26.24(a)(1) through (a)(4). The provision lists 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 former provision in § 26.24(a)(3), in particular, has led to confusion and misinterpretation of the requirements, to be corrected as noted below. Subparts E [Collecting Specimens for Testing], F [Licensee Testing Facilities], and G [Laboratories Certified by the Department of Health and Human Services] address the specific requirements for conducting the testing. The final rule reorganizes and amends former § 26.24(a)(1) through (a)(4) to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(c)(1) [Pre-access] amends former § 26.24(a)(1). Former § 26.24(a)(1) required pre-access testing within 60 days before the initial granting of unescorted access to protected areas or assignment to duties within the scope of this part. Section 26.31(c) of the final rule introduces 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 duties that 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 final rule specifies detailed requirements for conducting pre-access testing.

Section 26.31(c)(2) [For cause] and (c)(3) [Post event] clarifies and amends former § 26.24(a)(3), as follows:

Section 26.31(c)(2) [For cause] continues to require for-cause testing in response to any observed behavior or physical condition indicating possible substance abuse. The final rule also retains the former requirement for testing if the licensee or other entity receives credible information that an individual is engaging in substance abuse. Section 26.3 [Definitions] defines the term "substance abuse."

Section 26.31(c)(3) [Post event] amends the portion of former § 26.24(a)(3) that required drug and alcohol testing when an event involving a failure in individual performance leads to significant consequences. The final rule amends the former 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 former § 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 with the intent of this provision. Therefore, to clarify the intent of the provision, the final rule eliminates 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, requires post-event testing as soon as practical after significant events [as

listed in § 26.31(c)(3)(i) through (c)(3)(iii)] involving a human error that may have caused or contributed to the event. The final rule uses the term "human error" rather than the former term "worker's behavior" to emphasize that post-event testing is required for acts that unintentionally deviated from what was planned or expected in a given task environment (see 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 is required regardless of whether there was "reasonable suspicion" that the individual was abusing drugs or alcohol for the consequences listed in the section.

In addition, the NRC has added the second sentence of § 26.31(c)(3) to clearly delineate the scope of individuals who must be subject to post-event testing. Some licensees have misinterpreted the former provision as requiring the testing of all individuals who are involved in a significant event, including individuals whose behavior played no causal or contributing role in the event. For example, these licensees' FFD programs would require testing an individual who was exposed to radiation in excess of regulatory limits, 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 provision clarifies the original intent of this section by stating that only the individual(s) who committed the error(s) is subject to post-event testing.

Section 26.31(c)(3)(i) provides a threshold for the types of workplace personal injuries and illnesses for which post-event testing is required in response to implementation questions related to former § 26.24(a)(3). Some licensees have misinterpreted the former provision as requiring post-event testing for any personal injury, no matter how minor. This section clarifies 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,

"General Recording Criteria," 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 final rule, these 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. In the case of a significant injury or illness diagnosed by a physician or health care professional, a serious injury or illness does not need to result in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, or loss of consciousness. The final rule adds this clarification to reduce the number of unnecessary post-event tests performed for minor injuries and illnesses and meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.31(c)(3)(i) also includes 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 NRC acknowledges that in some cases it is difficult to detect illnesses and injuries that meet the 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 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 positive test results reflected the individual’s condition at the

time the event occurred rather than subsequent drug or alcohol use. Therefore, the final rule limits post-event testing to situations in which the licensee or other entity can determine that an injury or illness meets the threshold within four 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 section should not be misinterpreted as requiring post-event testing to be completed within four hours after the event. Section 26.31(c)(3) defines the time period after the event within which testing must be completed as "as soon as practical." The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.31(c)(3)(ii) retains the relevant language in the corresponding portion of former § 26.24(a)(3) without change.

Section 26.31(c)(3)(iii) retains the relevant language in the corresponding portion of former § 26.24(a)(3). However, as discussed with respect to § 26.31(c), the final rule eliminates the former qualifying phrase "if there is reasonable suspicion that the worker's behavior contributed to the event." The NRC has eliminated this phrase because it is preferable to determine the need for post-event testing using an objective standard based on the severity of the underlying event. The experience of the DOT with post-accident testing, for example, is that it is more effective to separate completely "for cause" concepts (such as "reasonable suspicion" of substance abuse) from post-event testing. Under the final rule's approach, if one of the events occurs that is defined in the regulations as requiring post-event testing, then that testing should be carried out irrespective of the presence or absence of any "reasonable suspicion" of substance abuse.

Section 26.31(c)(4) [Followup] retains the intent of former § 26.24(a)(4) but amends its language. The final rule eliminates the former phrase "to verify an individual's continued abstention from the use of substances covered under this part" because it could be

misinterpreted as limiting the substances for which followup testing is permitted to only those listed in § 26.31(d)(1) [Substances tested]. The final rule revises this phrase as "to verify continued abstinence from substance abuse" to clarify that FFD programs are permitted to conduct followup testing for any substances an individual may have abused, subject to certain additional requirements discussed with respect to § 26.31(d)(1)(i). Section 26.69 [Authorization with potentially disqualifying fitness-for-duty information] establishes detailed requirements for conducting followup testing, where they apply to licensees' and other entities' processes for granting and maintaining authorization. The final rule makes these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(c)(5) [Random] simplifies former § 26.24(a)(2) to define random testing as one of the conditions under which testing is required. The NRC has moved the detailed requirements for implementing random testing that were contained in former § 26.24(a)(2) to § 26.31(d) [General requirements for drug and alcohol testing] of the final rule. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

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

Section 26.31(d)(1) [Substances tested] retains the list of drugs for which testing must be conducted in former Section 2.1(a) in Appendix A to Part 26, but clarifies that for some drugs the testing is conducted to detect drug metabolites. The NRC has moved the provisions

detailing the circumstances in which testing for these substances must be performed (i.e., pre-access, post-event, random) to § 26.31(c) for organizational clarity. In addition, the section adds adulterants to the list of substances for which testing must be conducted, consistent with the addition of specimen validity testing requirements to the final rule, as discussed with respect to § 26.31(d)(3)(i). Section 26.31(d)(1)(i) retains the permission in the second sentence of former § 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.

Section 26.31(d)(1)(i)(A) retains the permission in former § 26.24(c) for licensees and other entities to add to the panel of drugs for which testing is required in § 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 provision also requires 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 is consistent with the definition of "illegal drugs" in former § 26.3 [Definitions].

Section 26.31(d)(1)(i)(B) retains the last sentence in former § 26.24(c). The provision requires licensees and other entities to establish appropriate cutoff levels for any additional substances for which testing will be conducted.

Section 26.31(d)(1)(i)(C) retains the requirement in former Section 2.1(c) in Appendix A to Part 26. The provision specifies that licensees and other entities must establish rigorous testing procedures for any additional drugs.

Section 26.31(d)(1)(i)(D) further clarifies the requirement in § 26.31(d)(1)(i)(C) for "rigorous testing procedures." The provision replaces the portion of former Section 1.1(2) in Appendix A to Part 26 that required licensees to obtain written approval from the NRC to test for additional drugs. The purpose of the former requirement was 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 former requirement also imposed a reporting burden. The final provision eliminates this reporting requirement and replaces it with requirements for an independent forensic toxicologist who has no relationships that could be construed as potential conflicts of interest to conduct the review that the NRC currently performs. The final rule requires 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. This section also specifies the required qualifications for the forensic toxicologist.

Certification of the assay and cutoff levels are not 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 the licensee or other entity uses the cutoff levels established in the HHS Guidelines for drug or drug metabolites; and (2) if the licensee and other entity received written approval of the NRC to test for the additional drug or drug metabolites before the implementation date of the final rule, which is 365 days after the date the final rule is published in the Federal Register. Certification by a toxicologist is unnecessary in these two circumstances because it would be redundant. By eliminating or modifying unnecessary requirements, while continuing to ensure that any drug testing conducted under Part 26 is scientifically sound and legally defensible, this provision meet Goal 5 of this rulemaking.

Section 26.31(d)(1)(ii) amends former Section 2.1(b) in Appendix A to Part 26. The provision permits 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 Controlled Substances Act that the licensee or other entity suspects the individual may have abused, as follows:

The section adds a reference to post-event testing for consistency with the intent of

former Section 2.1(b) in Appendix A to Part 26, which permitted testing for any illegal drugs during a for-cause test. The former rule included post-event testing within the definition of for-cause testing. The final rule uses a distinct term “post-event” testing to refer to the testing that is required following certain events as discussed with respect to § 26.31(d)(3). Therefore, it is necessary to add a reference to post-event testing to this section to retain the full intent of the former provision.

The section also adds a reference to followup testing, which permits 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 § 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. The NRC has made this change to strengthen the followup testing element of FFD programs by ensuring that followup testing would detect continued drug abuse. Therefore, this provision is consistent with Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The section retains the limitation in former Section 2.1(b) in Appendix A to Part 26 that permitted testing only for illegal drugs that the individual is suspected of having abused and extends that limitation to followup testing. The final rule extends this limitation to followup testing to protect donors’ rights to privacy, which is the same reason that the limitation was established in the former rule with respect to for-cause testing. Licensees and other entities are 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 former limitation on for-cause testing to followup testing meets Goal 7 of this rulemaking to protect the privacy rights

and other rights (including due process) of individuals who are subject to Part 26.

The final rule replaces the term “illegal drugs” in former 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 Controlled Substances Act. These schedules list drugs with abuse potential and include many drugs with legitimate medical uses that are not “illegal” when used with a valid prescription for medical purposes. Therefore, replacing the term “illegal drugs” with the reference to Schedules I–V of the Controlled Substances Act (CSA) more accurately characterizes the specific drugs for which testing is permitted. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.31(d)(1)(ii) also applies the new requirements in § 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 section requires that a forensic toxicologist certify the assays and cutoff levels to be used in testing for the additional drugs. The provision provides consistency with § 26.31(d)(1)(i)(D) and ensures that the testing is scientifically sound and legally defensible. The NRC has made this change to protect donors’ rights as it relates to minimizing the possibility of false positive test results. The provision also strengthens 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, the NRC has made this change to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to Part 26 and Goal 3 to improve the effectiveness and efficiency of FFD programs.

The NRC has added the last sentence of § 26.31(d)(1)(ii) 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 even if the quantitative test result falls 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. This basis 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 final rule specifically prohibits these practices, but adds, with respect to the proposed rule, an exception for a situation in which the specimen is dilute and the licensee or other entity has requested the HHS-certified laboratory to evaluate the specimen under §§ 26.163(a)(2) and 26.185(g)(3). The NRC has made these changes to meet Goal 7 of this rulemaking as it relates to protecting the rights of individuals (including due process) 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.

With respect to the proposed rule, the NRC has added § 26.31(d)(1)(iii) to the final rule to require the licensee or other entity to document the additional drug(s) for which testing will be performed in written policies and procedures. A public comment suggested that licensees and other entities should not screen for drugs in addition to those listed in paragraph (d)(1) of this section without identifying them in advance. The NRC agrees that informing individuals of the substances for which testing will routinely occur and the cutoff levels to be applied may deter abuse of those substances. Information about the drugs for which testing will occur, and their potential effects on job performance, is also an important part of the FFD training that

individuals must receive under § 26.29, to assist individuals in meeting their responsibilities under the rule. This added provision is also consistent with § 26.31(d)(3)(iii)(A) that requires licensees and other entities to document more stringent cutoff levels for drug testing than those specified in § 26.163 in written policies and procedures. However, the NRC does not agree that a licensee should be prohibited from testing for drugs in addition to those listed in the rule without identifying them in advance. Although deterring substance abuse is an important goal of the rule, detecting substance abuse is equally important. Therefore, both the former and final rules permit licensees to add drugs to the panel of substances for which they routinely test, as well as to conduct tests to detect any drugs listed on Schedules I-IV of the CSA in followup, post-event, and for-cause testing that the individual is suspected of abusing. The NRC has added this requirement to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.31(d)(2) [Random testing] reorganizes and amends the requirements for conducting random testing. These requirements appeared in former § 26.24(a)(2), as described in the following paragraphs.

Section 26.31(d)(2)(i) adds a 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. The NRC has added this provision because the NRC is aware of instances when individuals who believed they would have a positive test result if tested have been able to determine the days on which collections were being conducted. This determination 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 being 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 when 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 section requires 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 are 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, § 26.31(d)(2)(i)(A) adds a requirement that licensees and other entities 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. With respect to the proposed rule, the final rule clarifies that in the latter instance, the portions of each day and the days of the week must vary in a manner that cannot be predicted by donors. The NRC, after publishing the proposed rule, recognized the need for additional clarity in this provision to illustrate the NRC's intent. Therefore, the NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 23.31(d)(2)(i)(A) requires 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 requirement could include, but would not be limited to, stationing a mobile collection facility on site for some part of the day on 4 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 4 days in each calendar week. Maintaining the appearance that the collection site is active on more than half of the days in each week makes it more difficult for individuals to plan to subvert the testing process by leaving work when they believe specimens are being collected. By reducing the opportunities for individuals to subvert the testing process by having advanced warning that specimens are being collected, the requirements in § 26.31(d)(2)(i) and paragraph (A) of this section meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section 26.31(d)(2)(i)(B) amends the third sentence of former § 26.24(a)(2). This sentence required that specimens must be collected "at various times during the day." The final rule expands the former 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 former and final provisions is to ensure that individuals cannot predict the times they will be tested, as well as prevent them from perceiving that there are "safe" periods during which they will not be tested, which 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 also increases the rule's effectiveness in deterring substance abuse, which meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section 26.31(d)(2)(ii) retains the third sentence of former § 26.24(a)(2).

Section 26.31(d)(2)(ii) states that random testing must be administered on a nominal weekly frequency. The former requirement to collect specimens for random testing at "various times during the day" is retained in § 26.31(d)(2)(i)(B).

Section 26.31(d)(2)(iii) requires 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 § 26.27(b)(2). Section 26.31(d)(2)(iii) further clarifies 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 when 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 two hours to report for testing after notification. However, if no legitimate work, travel, or other demands would prevent an individual from immediately reporting for testing, the provision requires the individual to report as soon as he or she is notified. This provision strengthens FFD programs by further reducing opportunities for individuals to subvert the testing process and, therefore, meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section (d)(2)(iv) retains the portion of the first sentence of former § 26.24(a)(2) that required licensees to ensure that individuals subject to testing have an equal probability of being selected and tested. The final rule splits proposed § 26.31(d)(2)(iv) into two paragraphs after the first sentence of the proposed paragraph, and renumbers the subsequent paragraphs to accommodate this change. This reorganization is an effort to clarify the requirements of this section, consistent with Goal 6 of this rulemaking to improve clarity in organization and

language of the rule.

As a result of this renumbering, § 26.31(d)(2)(v) of the final rule amends the first sentence of former § 26.24(a)(2) to clarify that individuals who are off site when selected for testing and not reasonably available for testing when selected, must be tested at the earliest reasonable and practical opportunity. However, the final rule, with respect to the proposed rule, adds a clarification that individuals who are on site and not reasonably available for testing also must be tested at the earliest reasonable and practical opportunity. The NRC has made this change in response to a public comment, which suggested that the second sentence of proposed § 26.31(d)(2)(iv) could be interpreted as requiring individuals who are on site but not reasonably available for testing to be tested immediately. The commenter gave the example of an individual who is suited up for work in a radiologically controlled area from which he or she could not exit to be tested in a reasonable period of time. The NRC notes that in these cases, individuals who are on site but not reasonably be available for testing are required to report to the collection site as soon as reasonably practical after notification (emphasis on “notification”), under § 26.31(d)(2)(iii). In the given example, the supervisor would only notify the individual about testing after he or she is out of containment and has changed back to street clothes. If this were to occur at the end of the shift when collectors have left the site, this individual would not be notified that he or she must report for testing until the next time both the donor and the collectors are available to collect specimens for testing. Because there would be no known reason that this individual will test positive at the time of collection, any possible delays in testing should not compromise the performance objectives of the FFD program. However, the FFD program is responsible for preventing potential abuses brought on by such delays, which could include a supervisor protecting known substance abusers through improper notifications or delaying testing until completion of a critical job. Therefore, based on this analysis, the NRC has clarified this provision to reflect the public comment and clarify the NRC's intent, consistent

with Goal 6 of this rulemaking to improve clarity in the language of the rule.

The requirements of § 26.31(d)(2)(v) prohibit licensees and other entities from returning the names of the individuals who are offsite when selected for testing or who are on site and not reasonably available for testing when selected to the random testing pool without conducting a test, as has been the practice of some licensees. Returning these individuals' names to the random testing pool without conducting a test ensures that they are immediately eligible for another unannounced test, as required in § 26.31(d)(2)(vi), but does not ensure that all individuals who are subject to this part have an equal probability of being tested. Therefore, the requirement that individuals who are off site when selected for testing or who are on site and not reasonably available for testing when selected must be tested at the earliest reasonable and practical opportunity meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

The section includes 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 are not required to call an individual back to the site if he or she is off site when selected for testing. In addition, the provision does 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. This prediction would provide them with an opportunity to take actions to subvert the testing process, as discussed with respect to § 26.31(d)(2)(i). Therefore, the provision requires licensees and other entities to collect specimens from an individual who is off site when selected for testing or on site and not reasonably available for testing, in a manner that also ensures that the individual does not have advance notification that he or she has been selected

for testing. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.31(d)(2)(vi) of the final rule, renumbered from (d)(2)(v) in the proposed rule, retains the second sentence of former § 26.24(a)(2). This provision requires that an individual who has completed a test is immediately eligible for another random test.

Section 26.31(d)(2)(vii) of the final rule, renumbered from (d)(2)(vi) in the proposed rule, amends the last sentence of former § 26.24(a)(2). The NRC has made this change in response to licensee implementation questions with respect to the meaning of the term "workforce" in the former rule. These questions 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. This provision clarifies that the number of random tests that must be performed in a year must equal 50 percent of the population of individuals who are subject to random testing under the FFD program. If a common FFD program covers several sites, the "population" would include all individuals who are subject to the common FFD program. The population also includes individuals who have applied for authorization and who are subject to random testing under § 26.67 [Random drug and alcohol testing of individuals who have applied for authorization]. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.31(d)(3) [Drug testing] to the final rule to group requirements in one section that are related to the general administration of drug testing. The NRC has made this change because requirements that address this topic were dispersed throughout the former rule. Grouping them together in a section makes them easier to locate within the final rule. This reorganization meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(d)(3)(i) combines and modifies some of the requirements in former Section 1.1(3) in Appendix A to Part 26, former § 26.24(f), the first sentence of former Section 2.8(e)(1) in Appendix A, and former Section 2.8(a) and (b) in Appendix A to Part 26. These former provisions required licensees and other entities to use only HHS-certified laboratories to perform drug testing, except if initial tests were performed at a licensee testing facility. However, the final rule has clarified the first sentence of this section, with respect to the proposed rule, to include validity tests, validity screening tests, and initial validity tests. The NRC has retained other detailed requirements in these sections, but they are presented in the appropriate sections in Subparts E [Collecting specimens for testing], F [Licensee Testing Facilities], and G [Laboratories Certified by the Department of Health and Human Services] of the final rule. The agency has made these changes to meet Goal 6 of this rulemaking to improve the organizational clarity of the rule.

In addition, § 26.31(d)(3)(i) requires 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. However, the final rule clarifies the language of the proposed rule to require that any specimens that yield "positive initial drug test results or are determined by initial validity testing to be of questionable validity" must be subject to confirmatory testing by the laboratory. The final rule deletes the term "non-negative" from the proposed rule and adds the term "questionable validity" for the reasons discussed with respect to § 26.5 [Definitions]. The NRC has made these changes to meet Goal 6 of this rulemaking to improve the organizational clarity of the rule.

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 that, in 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 Final Revisions to the HHS Guidelines (66 FR 43876; August 21, 2001) to establish requirements for specimen validity testing performed by HHS-certified laboratories, 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 DOT regulations (49 CFR Part 40). Program experience gained after 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 former Part 26 contained a number of requirements related to specimen validity (e.g., the fifth sentence of former Sections 2.1(e), 2.4(f)(2), 2.4(g)(14) through (g)(16), and 2.7(d) in Appendix A to Part 26), the methods available to tamper with specimens have become more sophisticated after the rule was first published and more sophisticated methods of detecting tampering are necessary. Therefore, the final rule incorporates 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). The NRC has added these new requirements for specimen validity testing to strengthen FFD programs by improving current laboratory procedures to detect specimens that are dilute, adulterated, or substituted. This change is consistent with Goal 1 of this rulemaking 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. Attempts to tamper with a specimen provide clear evidence that the individual is not trustworthy and reliable. Also, these individuals' drug use may pose a risk to public health and safety and the common defense and security, as discussed with respect to § 26.23 [Performance objectives].

Section 26.31(d)(3)(ii) amends the first sentence of former § 26.24(d)(1). This sentence 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 final rule adds permission for licensees and other entities to perform initial validity testing at a licensee testing facility for the reasons discussed with respect to § 26.31(d)(3)(i). Subpart F [Licensee Testing Facilities] establishes detailed requirements related to specimen validity testing at licensee testing facilities.

Section 26.31(d)(3)(iii) is based upon the portions of former Section 2.7(e)(1) and (f)(2) in Appendix A to Part 26. These former sections established the cutoff levels for initial and confirmatory drug testing, respectively, which licensees must apply under the former rule. However, the final rule requires FFD programs to apply the updated cutoff levels specified in § 26.163(a)(1) for initial drug testing and § 26.163(b)(1) for confirmatory drug testing. The final rule clarifies the language of the proposed rule by adding that either the licensee testing facility or HHS-certified lab conducts the initial drug testing and the HHS-certified laboratory conducts the confirmatory testing. Consistent with the first sentence of former § 26.24(b), the second sentence of this provision permits FFD programs to implement more stringent cutoff levels than specified in the rule, but establishes additional requirements related to lower cutoff levels, as is discussed with respect to paragraphs (d)(3)(iii)(A) through (C). The NRC has relocated the permission in the first sentence of former § 26.24(b) to implement a broader panel of drugs to

§ 26.31(d)(1), as discussed with respect to that section. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(d)(3)(iii)(A) retains the third and fourth sentences of former § 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 final rule adds a requirement that the FFD program's written policy and procedures must document the FFD program's lower cutoff levels in the 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. The NRC has made this change to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.31(d)(3)(iii)(B) requires the uniform application of the FFD program's cutoff levels for drugs and drug metabolites, including any more stringent cutoff levels in all tests conducted under this part and equally to all individuals who are subject to testing, except as permitted under §§ 26.31(d)(1)(ii), 26.163(a)(2) for dilute specimens, and § 26.165(c)(2) for retesting specimens. As discussed with respect to § 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 NRC has added the section to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

The NRC has added § 26.31(d)(3)(iii)(C) to the final rule to specify requirements for establishing more stringent cutoff levels. Before implementing the more stringent cutoff levels, licensees and other entities are required to obtain certification from a forensic toxicologist that the more stringent cutoff levels are technically sound and legally defensible, with two exceptions. Certification by a forensic toxicologist is not required if: (1) 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 (2) if the licensee or other entity received written approval of the NRC to test for lower cutoff levels before the implementation date of this rule, which is 365 days after the date the final rule is published in the Federal Register. Certification by a toxicologist is unnecessary in these two circumstances because it would be redundant. The NRC has made this change to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements, while continuing to protect donors' right to accurate and reliable drug testing.

Section 26.31(d)(4) [Alcohol testing] updates former § 26.24(g) that contained general requirements for conducting alcohol testing. The update reflects other changes that have been made in the final rule. The NRC has amended the former cross-reference to Section 2.7(o)(3) in Appendix A to Part 26 to refer to § 26.91(a) in Subpart E [Collecting Specimens for Testing], which contains detailed requirements for conducting alcohol testing. The NRC has added the reference to oral fluids as acceptable specimens for initial alcohol testing to this section. The basis for adding oral fluids as acceptable specimens for initial alcohol testing is discussed with respect to § 26.83 [Specimens to be collected]. The NRC has changed the BAC at which a confirmatory test is required to 0.02 percent (from 0.04 percent) in the provision for consistency with the revised alcohol cutoff levels in § 26.99 [Determining the need for a confirmatory test for alcohol] and § 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 of the final rule. The agency has deleted reference to blood testing for alcohol because the final rule no longer permits donors to request blood testing for alcohol, as discussed with respect to § 26.83(a) of the final rule.

The NRC has added § 26.31(d)(5) [Medical conditions] to the final rule to address

circumstances when 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, when an individual's medical condition has made it inadvisable to implement testing procedures under the relevant requirements. Therefore, § 26.31(d)(5)(i) permits alternative specimen collection and evaluation procedures for rare instances when 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 is permitted to authorize an alternative evaluation procedure that may include, but is not limited to blood testing for alcohol. Section 26.31(d)(5)(ii) clarifies that necessary medical treatment may not be delayed in order to conduct drug and alcohol testing. These sections are consistent with the requirements of other Federal agencies and meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.31(d)(6) [Limitations of testing] retains and amends former Section 2.1(d) in Appendix A to Part 26. This former section stated 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 final rule adds examples of the types of analyses and tests that are prohibited without the donor's written permission. Although the NRC is not aware of any instances when 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. The NRC has added these examples to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.33 Behavioral observation.

The NRC has added § 26.33 to the final rule to emphasize that behavioral observation is a required element of FFD programs. The first sentence of § 26.33 requires behavioral observation of individuals subject to this subpart. The second sentence retains former § 26.22(a)(3), (a)(4), and (b), which stated that the individuals who perform behavioral observation must be trained. The third sentence of the section requires that individuals must report FFD concerns arising from behavioral observation to the appropriate personnel designated in the FFD program procedures. The NRC has added these requirements to the final rule to strengthen the behavioral observation element of FFD programs by increasing the likelihood that the licensees and other entities detect and appropriately address impairment and other adverse behaviors. These changes are consistent with Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.35 Employee assistance programs.

Section 26.35 amends former § 26.25 [Employee assistance programs (EAP)].

Section 26.35(a) retains the former provision without change and specifies that licensees and other entities shall maintain EAPs that offer confidential assessment, short-term counseling, referral services, and treatment monitoring to individuals who have problems that could adversely affect the individuals' abilities to safely and competently perform their duties. The provision also requires that the EAP be designed to achieve early intervention and provide for confidential assistance

The NRC has added § 26.35(b) to the final rule to clarify that licensees and other entities are not required to provide EAP services to C/V employees, including those who are working at a licensee's or other entity's facility. With respect to the proposed rule, the final rule clarifies that licensees and other entities are not required to provide EAP services to C/V employees whose work location is a licensee's or other entity's facility. This provision is

consistent with the interpretation of the former rule in item 13.1.4 of NUREG-1354. The final rule continues to require that C/V employees who are subject to Part 26 must have access to an EAP, and that licensees and other entities who rely upon the FFD program of a C/V continue to be required to ensure that the EAP of a C/V meets the requirements of this part.

The provision also states that licensees and other entities need not provide EAP services to individuals who have applied for but have not yet been granted authorization under Subpart C. Licensees and other entities are not required to provide an EAP to applicants for authorization because these individuals would not yet be performing duties that could affect public health and safety or the common defense and security. The NRC has added this clarification because applicants are subject to other requirements under the final rule as discussed with respect to § 26.4(h)

Section 26.35(c) amends the last sentence of former § 26.25. The provision emphasizes that the identity and privacy of an individual who seeks EAP services must be protected and clarifies the conditions under which EAP personnel may or must violate an individual's confidentiality. The final rule permits 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. By clarifying the NRC's intent with respect to EAP confidentiality, the provision meets Goal 6 of this rulemaking to improve clarity in the language of the rule because the former provision has been misinterpreted.

The last sentence of former § 26.25 required 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 some individuals who are subject to the rule have misinterpreted this phrase 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 former rule and who correctly permit EAP staff to make the determination of whether to report an individual's condition 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 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 section amends the last sentence of former § 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.

The NRC has added § 26.35(c)(1) to the final rule 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 assistance the individuals sought. The provision is necessary to eliminate some licensees' practices of requiring these reports, protect individuals' privacy, and strengthen the EAP element of FFD programs by eliminating a former barrier to self-referrals in some FFD

programs. The term “routinely” is used to indicate that the final rule permits 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 provision does 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 does not compromise individuals’ privacy.

The NRC has added § 26.35(c)(2) to the final rule to provide further clarity in the language of the rule with respect to the conditions under which EAP personnel are excepted from the confidentiality requirement in § 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 regulations in these circumstances. However, the final rule includes more detail with respect to the conditions and actions that an EAP professional is required to report to ensure that licensees, other entities, and individuals who are subject to the rule better understand the intent of the former and final provisions. The final rule requires 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 themselves or others. The phrase “substantive reasons to believe” is used to clarify that casual and/or contextually appropriate comments made by an individual during a counseling session are not 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. In 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 constitute substantive reasons to believe that the individual's condition poses an immediate hazard and must be reported.

The NRC has added § 26.35(c)(2)(i) through (iii) to the final rule to provide several examples of conditions and actions that require EAP personnel to provide a report about an individual who has self-referred to licensee or other entity management. Section 26.35(c)(2)(i) requires 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. Section 26.35(c)(2)(ii) requires 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 § 26.35(c)(2). Section 26.35(c)(2)(iii) requires 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 § 26.719(b)(1) through (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 duties that require the individual to be subject to this part. The examples included in these sections are illustrative, and 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 final rule.

For additional clarity, the NRC has added § 26.35(c)(3) to the final rule to cross-reference the provisions in the final rule that 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 §§ 26.69(d) and 26.77(b) of the final rule, those provisions require the licensee or other entity to take immediate action to prevent the individual from performing any duties that

require the individual to be subject to this part, 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 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 changes to former § 26.25 are consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, as well as Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.37 Protection of information.

Section 26.37 amends former § 26.29 that contained requirements for protecting the personal information that must be collected under Part 26. In general, this section of the final rule groups requirements related to the protection of personal information that were dispersed throughout the former rule to aid in locating these requirements in the final rule. The NRC has moved the records retention requirement in former § 26.29(a) to Subpart N [Recordkeeping and Reporting Requirements] of the final rule. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.37(a) combines and retains the first sentence of former § 26.29(a) and the second sentence of former Section 3.1 in Appendix A to Part 26. The final rule modifies the language of the proposed rule to require licensees and other entities to establish, use, and maintain a system of files and procedures that protects in the individuals' privacy. The NRC, after publishing the proposed rule, it recognized the need for more clarity in the language of this provision to illustrate the NRC's intent. Therefore, this change meets Goal 6 of the rulemaking to improve clarity in the language of the rule.

Section 26.37(b) amends former § 26.29(b) and divides it into several sections for clarity. The first sentence of the section amends the first sentence of former § 26.29(b) that

prohibited licensees and other entities from disclosing personal information collected under this part to any individuals other than those listed in the sentence. The final rule continues to permit disclosure of the personal information to the listed individuals and adds 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 individual. The NRC has added the permission to release the personal information to individuals who are not listed in the section with the written consent of the subject individual because some licensees have misinterpreted the former requirement as prohibiting them from releasing the personal information under any circumstances, except to the parties listed in this section. 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 NRC has added the explicit permission for licensees and other entities to release personal information when an individual consents to the release, in writing, to meet Goal 7 of this rulemaking to protect the privacy rights and other rights (including due process) of individuals who are subject to Part 26.

Section 26.37(b)(1) through (b)(8) lists the individuals to whom licensees and other entities are permitted to release personal information about an individual. Section 26.37(b)(3), (b)(4), and (b)(8) retains unchanged the permission for the release of information to NRC representatives, appropriate law enforcement officials under court order, and other persons as required by court order. Section 26.37(b)(1), (b)(2), (b)(5), (b)(6), and (b)(7) amends the related requirements contained in former § 26.29(b) to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. The specific changes to former § 26.29(b) include the following:

Section 26.37(b)(1) retains the permission for the release of information to the subject individual and his or her designated representative. The provision adds requirements for the

individual to designate his or her representative in writing and specify the FFD matters to be disclosed. The NRC has made these changes in response to implementation questions from licensees. Licensees have sought guidance from the NRC related to the way an individual must "designate" a representative.

Section 26.37(b)(2) retains the permission for the release of information to the licensee's or other entity's MROs. The final rule also permits the release of information to MRO staff members for consistency with § 26.183(d), which permits MRO staff to serve some MRO functions under the direction of the MRO. MRO staff require access to the personal information in order to perform their duties. The role of MRO staff in FFD programs is discussed with respect to § 26.183(d) of the final rule.

Section 26.37(b)(5) amends the former reference to licensee representatives who have a need to have access to the information in performing assigned duties. The former rule referred only to individuals who are performing audits of FFD programs. As a result, some licensees have misinterpreted the former rule as limiting the release of personal information only to such individuals. This was not the intent of the provision. Rather, the NRC intended that licensees and other entities were permitted to release information to their representatives who must have access to the personal information in order to perform assigned duties.

With respect to the proposed rule, the final rule modifies proposed § 26.37(b)(5) to clarify the NRC's intent that the only licensee or other entity representatives who may have access to the personal information collected under this part are persons who have a need for that information to implement the requirements of the rule. The NRC made this change to provide greater assurance that personal information, such as medical records that an individual has submitted to the MRO to document prescription medication or a "shy bladder" situation, is not released to persons who do not have assigned duties under the FFD program that specifically require access to that information. Reviewing officials, MROs, SAEs, and other

FFD program personnel, as well as auditors, require access to some personal information about individuals in order to perform their assigned duties to implement the FFD program. Human resources personnel may need to know that an individual has violated the FFD policy, if the licensee or other entity terminates an individual's employment in response to an FFD policy violation, but do not need access to the personal information collected about the individual under the FFD program to carry out the process of terminating the individual's employment. The NRC has determined that this additional clarification is necessary to provide further protection of the privacy of persons who are subject to the rule.

Section 26.37(b)(6) and (b)(7) amends the portion of former § 26.29(b) that referred to "persons deciding matters on review or appeal." The NRC has amended the provision 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 former § 26.28 [Appeals], as well as whether information could be released in a judicial proceeding that the subject individual did not initiate. The final rule clarifies that the permission includes individuals who are presiding in a judicial or administrative proceeding, but only if the subject individual in § 26.37(b)(6) initiates the proceeding. Section 26.37(b)(7) covers "persons deciding matters under review in § 26.39" [Review process for fitness-for-duty policy violations], as discussed with respect to that section. The NRC has made these changes to meet Goal 6 of this rulemaking relating to improving clarity in the organization and language of the rule.

The NRC has added § 26.37(c) to the final rule 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 provision clarifies former § 26.29(b) because some licensees have misinterpreted the former 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 NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.37(d) through (f) retains several requirements related to the protection of information in the former rule but moves them into this section for organizational clarity. Section 26.37(d) combines requirements in former § 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. However, the final rule modifies the language of the proposed rule by specifying that it is the FFD program that is required to promptly provide all requested records. The NRC has made this change to meet Goal 6 of the rulemaking to improve clarity in the language of the rule. The final rule also adds "collection site" and "SAE" to the list of entities who must provide records to an individual or his or her designated representative. The final rule also expands the proposed language to specify the types of records that must be provided. The examples given for the types of records that must be provided to the individual are illustrative, but are not comprehensive of all the types of records that must be provided upon request. The agency has made these changes in response to public comment, to clarify the rule language, to ensure that individuals and representatives can verify the accuracy of FFD records, and to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals subject to Part 26.] Section 26.37(e) and (f) retains former Section 3.1 in Appendix A to Part 26 and the last sentence of former § 26.29(b), respectively.

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

Section 26.39 amends former § 26.28 [Appeals] and separates it into several sections. The change from the former section heading eliminates the implication that the internal management review is a legal proceeding. The agency has added several requirements to clarify and strengthen individuals' rights during the review, consistent with Goal 7 of this

rulemaking, as described in the following paragraphs.

Former § 26.28 required 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. Section 26.39(a) retains the requirement that the review must be impartial and adds a requirement that the review must be objective. The NRC has added the requirement for an objective review 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 was required under former § 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 requirement for the review to be both impartial and objective emphasizes the NRC's intent that the review process be effective.

In keeping with revisions to several other sections that are intended to counter subversion of the testing process, § 26.39(a) extends this opportunity to request a review to all FFD violations, including, but not limited to, violations based upon confirmed positive, adulterated, or substituted, or invalid validity test results. The section also clarifies 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 positive 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 also enhances program credibility.

Section 26.39(b) specifies 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. The provision also requires that the procedures must state that the individual may submit additional relevant information as part of the review process. This clarification is necessary because experience with implementing former § 26.28 has indicated that individuals do not understand the purpose of the review process and their associated rights in some cases.

Section 26.39(c) specifies that the procedure must ensure that the individual who conducts the review is not associated with the administration of the FFD program. The final rule modifies the proposed rule by requiring that only one representative of the licensee's or other entity's management shall conduct the review. The final rule allows only one individual to conduct the review in response to a public comment that stated that the review process required by this section should be consistent with that required by 10 CFR 73.56(e) (personnel access authorization) because this would simplify licensee procedures and would improve the consistency between FFD requirements and access authorization requirements. In specifying that the reviewer may not be anyone associated with the administration of the FFD program, including anyone who made the initial determination that the individual violated the FFD policy, the final rule strengthens the impartiality and objectivity of the review process in order to further enhance individuals' rights. The NRC has made these changes to meet Goal 3 of the rulemaking to increase the effectiveness and efficiency of FFD programs, and Goal 7 to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.39(d) adds 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 is necessary because the final rule permits licensees and other entities to share and rely on information gathered by other Part 26 programs to a greater extent than is currently possible. Therefore, incorrect records related to an FFD policy violation could

significantl inhibit an individual from further employment under a Part 26 program if this information is transmitted to other licensees and entities who are considering whether to grant authorization to an individual. The requirement to delete or correct any records associated with an FFD policy violation that has been overturned will protect individuals from such potential adverse consequences.

Section 26.39(e) of the final rule amends the last sentence of former § 26.28. This sentence stated that licensees and other entities are not required to provide a review procedure to C/V employees and applicants when the C/V is administering its own drug and alcohol testing. The final rule amends the former paragraph in response to implementation questions from licensees who have asked whether the former provision excuses them from providing a review process for C/V employees at any time, including situations when the FFD policy violation was determined as a result of testing conducted by the licensee. The final rule revises this sentence to clarify that the licensee or other entity need not provide a review process if the C/V's drug and alcohol testing program identified the FFD violation to be reviewed. If the licensee's drug and alcohol testing determined the FFD violation, the licensee is required to provide the impartial and objective review. The final rule modifies the proposed rule to state that the licensee need not provide a review procedure to a C/V subcontractor when the FFD policy violation was determined under a C/V's program. These changes are consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.41 Audits and corrective action.

Section 26.41 of the final rule renames and amends former § 26.80 [Audits]. The NRC has added the phrase "and corrective action" to the section heading 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 final rule reorganizes

the audit requirements in former § 26.80, and moves several audit and inspection requirements into this section that were addressed in Appendix A to Part 26. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.41(a) [General] of the final rule amends the last sentence in former § 26.80(a). This sentence stated that licensees retain responsibility for the effectiveness of C/V programs and the implementation of appropriate corrective action. The final rule revises this requirement to include HHS-certified laboratories, as well as any C/V FFD program elements and FFD programs that the licensee or other entity relies upon, consistent with the intent of the former requirement. The final rule has added a phrase to the proposed rule that requires licensees to be responsible for the continuing effectiveness of any FFD program services a subcontractor provides to the C/V. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.41(b) [FFD program] of the final rule amends the required audit frequency in former § 26.80(a). (Other provisions of § 26.41 address the other requirements contained in former § 26.80(a), as discussed with respect to the sections of the final rule that address those topics.) The final rule decreases the former 12-month FFD program audit frequency to a nominal 24-month frequency, which grants 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 NRC decreased the audit frequency to 24 months to relieve this burden and to be consistent with the NRC's schedule for inspecting FFD programs. The change is consistent with Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Although the final rule decreases the required audit frequency, licensees and other entities are 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 final rule requires licensees and other entities to consider FFD performance, including but not limited to, the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, and previous audit findings. The provision 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 or did not take, or changes in processes. The purpose of these focused audits is 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 audit requirement ensures that any programmatic problems that may result from significant changes in personnel, procedures, or equipment are detected and corrected on a timely basis. By requiring more frequent audits of FFD program performance that may require closer monitoring than a nominal 24-month frequency would provide, these changes meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.41(c) [C/Vs and HHS-certified laboratories] of the final rule amends the audit and inspection requirements that are contained in the second sentence of former § 26.80(a) and the third sentence of Section 2.7(m) in Appendix A to Part 26, as follows:

Section 26.41(c)(1) further amends the requirement in former § 26.80(a) for annual audits of C/V FFD programs and program elements and HHS-certified laboratories. The former annual audit frequency is 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 are audited under § 26.41(b). Retention of the annual audit requirement for C/Vs whose personnel work off site meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FD programs. The provision is necessary to ensure that the services provided continue to be effective because other means of monitoring their effectiveness, such as daily oversight, are unavailable. The section also retains the annual audit requirement for HHS-certified laboratories. The NRC has retained this audit frequency because of the key role the laboratories play in the overall effectiveness of Part 26 programs. Retention of these annual audit requirements in the section denies the petition for rulemaking (PRM-26-1) submitted by Virginia Power on December 30, 1993.

Section 26.41(c)(2) relaxes some requirements related to annual audits and inspections of the HHS-certified laboratories that licensees and other entities rely upon for drug testing services. The final rule permits 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 no longer requires licensees and other entities to audit the effectiveness of services that HHS inspectors review. The former rule contained a number of requirements that are inconsistent with the requirements for drug testing under other Federally mandated programs. For example, the former rule permitted donors to request confirmatory alcohol testing of a blood specimen at an HHS-certified laboratory, which other Federal agencies do not permit. Also, some of the cutoff levels established in the former rule are higher, in the case of testing for marijuana metabolite, or lower, in the case of testing for opiates, than those of 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 HHS inspections do not address these services. The final rule eliminates the majority of these discrepancies. Therefore, the annual audits of HHS-certified laboratories by licensees that have been necessary under the former rule would be redundant under the final rule, except in certain conditions described below. The NRC has made these changes to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.41(c)(2) continues to require licensees and other entities to conduct annual audits of any services provided to the licensee or other entity that the annual HHS-certification review did not address. The NRC has retained this annual audit requirement because § 26.31(d) retains the permission in the former 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 under the final rule, the licensee or other entity is required to ensure that annual audits of the HHS-certified services related to those cutoff levels and drug tests are performed.

The NRC has added the last sentence of § 26.41(c)(2) to clarify the scope of the former audit requirements. The final rule does 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 is 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, § 26.187 [Substance abuse expert] requires the SAE to monitor the substance abuse treatment of individuals who require it and the SAE would have the

qualifications and information necessary to assess the quality of the treatment services an individual receives. The SAE has the authority to seek other services on behalf of the FFD program if he or she identifies weaknesses in a treatment program. Therefore, the NRC has made these changes to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.41(d) [Contracts] of the final rule incorporates and amends the requirements of former Section 2.7(m) in Appendix A to Part 26 and others that addressed 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 former Section 2.7(m) in Appendix A to Part 26 that related to NRC inspections of HHS-certified laboratories have been moved to § 26.821 [Inspections] in Subpart O [Inspections, violations, and penalties] of the final rule, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.41(d)(1) amends the second sentence of former Section 2.7(m) in Appendix A to Part 26. The former section required 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 final rule retains the former requirement with respect to HHS-certified laboratories and expands 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 provision extends the former 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. The licensee or other entity may determine that an unannounced audit would provide the most effective means to investigate these allegations. This provision ensures that the licensee's or other entity's contract with the C/V permits the unannounced audit as well as access to any information necessary to conduct the audit. Therefore, the NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC had added § 26.41(d)(2) 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 provision responds to several incidents when parties under contract to licensees did not permit Part 26 auditors to remove documents from a premises of a C/V that were necessary to document audit findings, develop corrective actions, and ensure the effectiveness of the corrective actions. Therefore, the new requirement meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs. The provision permits HHS-certified laboratories to reasonably limit the use and dissemination of the documentation that auditors copy and take off site. This change meets Goal 7 of this rulemaking to the protect privacy of individuals who are subject to Part 26 and protects the trade secrets of HHS-certified laboratories who are subject to auditing under the final rule.

Section 26.41(d)(3) amends the third sentence of former Section 2.7(m) in Appendix A to Part 26. This sentence required licensees and other entities to carry out inspections and evaluations of the procedural aspects of an HHS-certified laboratory drug testing operations before awarding a contract to the laboratory. The final rule adds a cross-reference to § 26.41(g). Section 26.41(g) permits licensees and other entities to forego the otherwise

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

Section 26.41(e) [Conduct of audits] of the final rule retains the requirements in former § 26.80(b).

Section 26.41(f) [Audit results] of the final rule retains the portion of former § 26.80(c) that required 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 final rule adds two requirements. The second sentence of § 26.41(f) specifies the required content of audit reports, including identification of any conditions that are adverse to the proper performance of the FFD program, the cause of the condition(s), and recommended corrective actions. The third sentence of the section requires licensees and other entities to review the audit findings and take corrective actions, including reauditing of indicated deficient areas, to preclude, within reason, repetition of the condition. The final rule adds these two sentences for consistency with Criterion XVI in Appendix B to 10 CFR Part 50 [Domestic licensing of production and utilization facilities] to indicate that the corrective action programs of licensees and other entities must include FFD audit reports. Some licensees have handled FFD audit reports outside of their normal corrective action programs that address other conditions adverse to quality. As a result, some corrective actions for FFD program weaknesses have not been timely or effective. Therefore, the final rule adds these requirements to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has deleted the last sentence of former § 26.80(c) that referred to the requirements for auditing HHS-certified laboratories in Appendix A to Part 26 because it is redundant with § 26.41(c). The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.41(g) [Sharing of audits] of the final rule responds to licensees' implementation questions related to the third and fourth sentences in former § 26.80(a) that permitted licensees and other entities to accept audits of C/Vs that other FFD programs conduct. The section clarifies the former 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, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions."

Section 26.41(g) amends the former provision to incorporate specific permission for licensees and other entities to jointly conduct audits as well as rely on one another's audits. The NRC has also added a reference to HHS-certified laboratories to indicate the applicability of these permissions to licensees' and other entities' audits of HHS-certified laboratories. These changes are consistent with the guidance issued by the NRC in the documents referenced above and current licensee practices. Therefore, the NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.41(g)(1) and (g)(2) to the final rule 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 is not permitted to rely on the shared audit with respect to the lower cutoff levels and is 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 that use the same cutoff levels). These provisions are consistent with the guidance issued by the NRC in the documents referenced above and current licensee practices. Therefore, the NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

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

Section 26.41(g)(4) retains the fourth sentence of former § 26.80(a). This provision requires licensees and other entities to retain copies of the shared audit reports.

The NRC has added § 26.41(g)(5) to the final rule. The provision permits licensees and other entities to immediately obtain drug testing services from another HHS-certified laboratory, subject to certain conditions, if the laboratory used by the licensee or other entity loses its certification. Within 3 months of obtaining services from the replacement laboratory, the section requires the licensee or other entity to ensure that an audit is conducted of any aspects of the laboratory's services that the licensee or other entity use that have not been audited within the past 12 months by another licensee or entity who is subject to this subpart. This provision enhances the effectiveness of FFD programs by ensuring that drug testing will 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 is ensured 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 NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Subpart C – Granting and Maintaining Authorization

Throughout Subpart C [Granting and Maintaining Authorization], the final rule makes minor clarifications to the proposed rule based on public comment, to accommodate conforming changes, and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

One clarification that the final rule makes in numerous sections in this subpart is to state that licensees or other entities subject to this subpart shall "ensure" that a requirement under this subpart has been met. This language differs from that of the proposed rule, which stated that the licensee or other entity shall explicitly perform the activity (i.e., obtain, review, conduct, complete) to meet the requirement. For example, in § 26.55(a)(1), the proposed rule stated that the licensee or other entity shall "obtain and review a self-disclosure." The final rule states that the licensee or other entity shall "ensure that a self-disclosure has been obtained and reviewed" This modified language clarifies the NRC's intent that licensees or other entities may rely on other entities to assist in performing the activities necessary to meet the requirements of this subpart. For example, many licensees rely on contractors to conduct the suitable inquiry required under § 26.63. However, the final rule retains the language of the proposed rule in § 26.69(b) for the reasons discussed with respect to that paragraph. In another change from the proposed rule text, the NRC has eliminated the term "non-negative" and replaced it with the phrase "positive, adulterated, or substituted" for the reasons discussed with respect to § 26.5 [Definitions].

The final rule also makes more substantive changes to the proposed rule in this subpart

because of public comment or to improve clarity in the organization and language of the rule. The substantive changes in this subpart can be found in §§ 26.51; 26.53(d) through (i); 26.57(b); 26.61(c) and (d); 26.63(c), (c)(3), (d) and (f); 26.65(c), (c)(2) , (d)(1)(i), (d)(2)(ii), (e) and (f); and 26.69(c), (c)(1) and (e)(1). These changes are discussed in detail below. However, other than the changes mentioned above, the final rule adopts the provisions of this subpart as proposed, without change.

Section 26.51 Applicability.

The final rule amends § 26.51 of the proposed rule to describe the applicability of the subpart. The NRC has changed the heading of this section from “Purpose” to “Applicability” because the NRC has revised the content of the section to specify the licensees, entities, and categories of individuals to whom the requirements Subpart C apply by using cross-references to the relevant paragraphs in §§ 26.3 [Scope] and 26.4 [FFD program applicability to categories of individuals]. The NRC made this change in response to public comments requesting this clarification in the rule text and to meet Goal 6 of this rulemaking.

Section 26.53 General provisions.

The NRC has added § 26.53 [General provisions] to the final rule to provide an overview of the requirements and process for determining when individuals may be granted and maintain authorization. With respect to the proposed rule, paragraph (e) has been added to this section to specify the requirements for relying on the FFD program of a C/V when granting or maintaining authorization. Paragraph (f) specifies that licensees and other entities may not rely on FFD programs under Subpart K [FFD programs for Construction] of this rule to meet the requirements of this subpart. The reasons for adding these paragraphs are discussed with respect to the specific paragraphs.

Section 26.53(a) of the final rule introduces four new terms to Part 26: "initial authorization," "authorization update," "authorization reinstatement," and "authorization with potentially disqualifying FFD information." The final rule uses these terms to describe categories of requirements for granting authorization. These categories are based on whether an applicant has previously held authorization under Part 26 and the length of time that has elapsed after the individual's last period of authorization ended, and are described in § 26.55 [Initial authorization], § 26.57 [Authorization update], § 26.59 [Authorization reinstatement], and § 26.69 [Authorization with potentially disqualifying fitness-for-duty information]. Section 26.53(a) directs licensees or other entities to use the criteria for granting authorization to individuals found in §§ 26.55, 26.57, 26.59, or 26.69, depending on which of these sections applies to the individual seeking authorization. The former rule in § 26.27 [Management actions and sanctions to be imposed] discussed actions that the licensee must take before initially granting access or assigning specified duties to an individual, but did not use the concepts of "initial authorization," "authorization update," "authorization reinstatement," or "authorization with potentially disqualifying FFD information." The final rule uses these concepts to focus the requirements for authorization more precisely on whether the individual has an established record (i.e. authorization history) in the industry. The NRC also uses these concepts to specify the amount of original information-gathering activities licensees or other entities are required to perform, according to whether previous FFD programs have collected information about the individual. In addition, the NRC uses similar concepts in access authorization requirements found in 10 CFR 73.56 [Personnel access authorization requirements for nuclear power plants] and access authorization orders issued by the agency to nuclear power plant licensees. The NRC has incorporated these concepts into Part 26 to increase the consistency between the related regulations in accordance with Goal 4 of this rulemaking.

Section 26.53(b) of the final rule defines the meaning of the term "interruption" which is

used in § 26.57 [Authorization update] and § 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 shall calculate an interruption in authorization as the total number of days falling between the day the individual's last period of authorization ended and the day the licensee or other entity grants authorization to the individual. Section 26.53(b) also specifies that if potentially disqualifying FFD information is disclosed or discovered about an individual, licensees and other entities must implement the applicable requirements in § 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 §§ 26.55, 26.57, or 26.59.

Section 26.53(c) of the final rule references the FFD training requirements in § 26.29 [Training] and the fatigue training requirements in § 26.203(c) [Training and examinations] to clarify that all individuals who are subject to Subpart C 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. This provision references the training requirements for organizational clarity because they apply to the authorization process. As discussed in the preamble to the proposed rule, stakeholders requested that the regulation present requirements in the order in which they would apply to licensees' and other entities' FFD processes. The NRC has added this paragraph to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.53(d) of the final rule permits licensees and other entities to rely on other licensees' or entities' FFD programs and program elements to meet the requirements of this subpart for granting and maintaining authorization. Section 26.53(d) expands upon a section of the former rule that similarly permitted licensees and other entities to accept and rely on other FFD programs and program elements. Specifically, former § 26.24(a)(1) permitted licensees to

accept results from drug and alcohol tests that were administered under another Part 26 program within the past 60 days. Consistent with the principle of permitting licensees to accept and rely on other Part 26 programs in their authorization decisions, guidance contained in NUREG-1385, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions," 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 final rule substantially increases the specificity of the requirements that licensees or other entities must meet for granting authorization and establishes detailed minimum standards that all programs must meet. The agency designed these detailed minimum standards to address recent changes in industry practices that have resulted in a more transient workforce. Because the FFD programs of licensees and other entities will be substantially more consistent than in the past under these detailed standards, permitting licensees and other entities to rely on other FFD programs to meet the rule's requirements is reasonable and appropriate. Section 26.53(d) eliminates unnecessary redundancies in the steps required to grant authorization to an individual who is transferring from one FFD program to another, consistent with Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. With respect to the proposed rule, the final rule specifies that the receiving FFD program shall ensure that the program elements to which the individual is subject under the transferring FFD program remain current. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking 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.

In response to public comment, the final rule adds paragraph (e) to § 26.53 to clarify the

relationship between licensees' and other entities' FFD programs and those of C/Vs. Section 26.53(e) retains the permission in former § 26.23 [Contractors and vendors] for licensees to rely upon C/Vs' FFD programs that have been formally reviewed and approved by the licensee. The paragraph also permits the licensees and other entities in § 26.3(a) through (c) to rely on a C/V's FFD program elements that meet the requirements of Part 26. For example, some C/Vs ensure that their employees receive initial and refresher FFD training so that, when the employee is assigned to work on a contract that requires him or her to have unescorted access to a nuclear power plant protected area, it is unnecessary for the licensee to provide FFD training to the C/V's employee in order to grant unescorted access to this individual. The final rule adds this permission to rely on a C/V's FFD program elements to codify a long-standing industry practice that has been endorsed by the NRC and to provide clarity in the language of the rule.

Section 26.53(e)(1) permits a C/V to grant, maintain, deny, or unfavorably terminate an individual's authorization under the C/V's FFD program. As defined in § 26.5, granting authorization in this case means that a C/V has determined that the individual has met the requirements in this subpart and is eligible to have the types of access and perform the duties specified in § 26.4. Maintaining authorization under a C/V's FFD program means that the individual continues to meet the requirements of this subpart and be eligible to perform the duties specified in § 26.4. However, the second sentence of § 26.53(e)(1) retains the intent of the provisions in former § 26.23 that placed responsibility on licensees for ensuring that individuals who are "performing activities within the scope of this part" meet the requirements in Part 26. However, the final rule updates the terminology used to convey this intent and adds cross-references to other sections of the rule for clarity and consistency with other rule changes.

Section 26.53(e)(2) further clarifies the relationship between authorization under a C/V's

FFD program and authorization under the FFD programs of licensees and other entities in § 26.3(a) through (c). This provision addresses circumstances when a C/V's FFD program determines that an individual does not meet the requirements of this subpart to be granted or maintain authorization and denies or unfavorably terminates the individual's authorization under the C/V's program. The rule requires that if the C/V's FFD program denies or unfavorably terminates the authorization of an individual who is performing the duties for a licensee that are listed in the specified sections of § 26.4, the C/V must inform the affected licensee or other entity of the denial or unfavorable termination. In this case, the licensee or other entity shall, on the day the licensee receives the information from the C/V, deny or unfavorably terminate the individual's authorization or implement the applicable process in § 26.69 to maintain the individual's authorization. For example, if a C/V's employee is convicted of selling illegal drugs and reports the conviction to the C/V, the C/V would unfavorably terminate this individual's authorization under the C/V's FFD program. If the individual was also assigned to a contract that required him or her to have unescorted access to the protected area of a nuclear power plant at the time he or she was convicted, this provision requires the C/V to inform the FFD program of the licensee or other entity of the conviction. The licensee would then either terminate the individual's unescorted access on the day that the licensee or other entity receives the information from the C/V or, in unlikely circumstances, may implement the process established in § 26.69(d) for determining whether an individual may maintain authorization after potentially disqualifying FFD information is disclosed or discovered. This provision codifies a long-standing industry practice that has been endorsed by the NRC and adds clarity in the rule language. The NRC has also added this requirement in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking 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.

The final rule has added § 26.53(e)(3) to the final rule to explicitly permit the licensees and other entities in § 26.3(a) through (c) to rely on a C/V's FFD program and program elements, or a combination of program elements from the licensee's or other entity's FFD program and the C/V's FFD program, to satisfy the requirements of Subpart C for maintaining an individual's authorization. This paragraph repeats the language in § 26.53(d), which permits licensees and other entities to rely on one another's FFD programs and program elements, but applies it to C/V FFD programs and program elements for additional clarity in the language of the rule. The final rule also clarifies that the receiving licensee's or other entity's FFD program shall ensure that the program elements to which the individual is subject under the C/V's FFD program remain current. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking 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.

The NRC has also added § 26.53(f) to the final rule to prohibit licensees and other entities from relying on an FFD program that has been implemented under Subpart K [FFD Programs for Construction] of this part when granting authorization to an individual. This prohibition is necessary because Subpart K permits the licensees and other entities specified in § 26.3(c) greater flexibility in establishing and implementing an FFD program than is permitted in Subpart C. For example, Subpart K does not require the licensees and other entities in § 26.3(c) to conduct a suitable inquiry of individuals who are permitted to perform the duties described in § 26.4(f). Therefore, in order to grant authorization to such an individual to have the types of access or perform the duties in § 26.4(a) or (b), for example, a licensee in § 26.3(a)

would be required to ensure that a suitable inquiry has been completed under § 26.63. However, this new provision would permit a licensee or other entity to rely on the program elements of a Subpart K FFD program if the program elements meet the applicable requirements of Subpart C. For example, if a Subpart K program included suitable inquiry requirements and implemented them under § 26.63, a licensee or other entity could rely on those suitable inquiry results when granting authorization under Subpart C. This section satisfies Goal 3 of this rulemaking by improving the effectiveness and efficiency of FFD programs.

The NRC has added 26.53(g) to the final rule to require licensees and C/Vs to identify any FFD violation to any licensee who has relied or intends to rely on the FFD program element that is determined to be in violation of this part. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking 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.

In the final rule, the NRC has added a new provision in § 26.53(h) to prohibit licensees and other entities from initiating any actions under Subpart C, such as beginning to gather information about the individual's authorization history from other licensees or entities, without the knowledge and consent of the individual who is applying for authorization. The new provision in the final rule also informs individuals that they may withdraw consent at any time, and specifies the actions that licensees and other entities must take if an individual withdraws his or her consent. The NRC has added this provision to provide additional protection of individuals' privacy by ensuring that licensees and other entities do not gather personal information about an individual without his or her permission. The requirements to inform the

individual that he or she may withdraw consent and for licensees and other entities to inform the individual of what information will be documented and shared with other licensees or entities following a withdrawal of consent are necessary to protect individuals' other rights under the rule, including due process. Therefore, this provision meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals subject to Part 26. This provision is meets Goal 4 of this rulemaking to improve consistentency 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.

The NRC has added § 26.53(i) to the final rule to require licensees and other entities to inform individuals applying for authorizations of the actions related to providing and sharing personal information that are sufficient cause for denial or unfavorable termination of authorization. The actions that are sufficient cause for denial or unfavorable termination of authorization include refusal to provide written consent, as specified in § 26.53(i)(1), and refusal to provide or the falsification of any personal information required under this subpart, including the failure to report any previous denial or unfavorable termination of authorization, as specified in § 26.53(i)(2). These provisions were moved from § 26.63(d) and § 26.61(d) of the proposed rule, respectively. The NRC has added § 26.53(i)(3) and (i)(4) to specify that a refusal to provide written consent for the sharing of personal information with other licensees or C/Vs, as required in § 26.53(h), and a failure to report any legal actions, respectively, are also sufficient cause for denial or unfavorable termination of authorization. Also, the NRC has made these changes to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking 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 26.55 Initial Authorization.

The NRC has added § 26.55 to the final rule, which defines the category of "initial authorization" requirements as applying 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 ended favorably.

Two considerations support the mandate 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, mandating that individuals whose last period of authorization ended 3 or more years previously must satisfy the same requirements as individuals who have never held authorization increases the consistency of Part 26 with the related access authorization requirements, consistent with Goal 4 of this rulemaking.

Section 26.55(a)(1) requires the licensee or other entity, before granting initial authorization to an individual, to ensure that a self-disclosure has been obtained and reviewed in accordance with the applicable requirements of § 26.61 [Self-disclosure and employment history]. As discussed with respect to § 26.61, the self-disclosure and employment history requirements mandate that the individual report violations, if any, involving drugs or alcohol and

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

Section 26.55(a)(2) requires the licensee or other entity to ensure that a suitable inquiry has been completed under the applicable requirements of § 26.63 [Suitable inquiry] before granting initial authorization to an individual. The requirement is similar to that in § 26.27(a)(2) of the former rule that a suitable inquiry must be completed addressing the topics that are specified in § 26.27(a)(2). The discussion of § 26.63 in this document compares the topics that the suitable inquiry must address under the former rule with the topics that it addresses under the final rule. Section 26.63(f)(1) specifies that the suitable inquiry for an initial authorization must address the shorter period of either the past 3 years or the interval of time that has elapsed since the individual's eighteenth birthday.

Section 26.55(a)(3) requires the licensee or other entity to ensure that the individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65 [Pre-access drug and alcohol testing] before granting initial authorization to an individual. Former § 26.24(a)(1) required testing within the 60 days before initially granting unescorted access to protected areas or assignment to activities within the scope of Part 26. The discussion of § 26.65 in this document compares the pre-access drug and alcohol testing requirements for initial authorization in this rule to the requirements in the former rule. Section 26.65 requires 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.

Section 26.55(a)(4) requires the licensee or other entity also to ensure that the individual has been subject to random drug and alcohol testing under the applicable requirements of § 26.67 [Random drug and alcohol testing of individuals who have applied for authorization]. Former § 26.64(a)(2) required unannounced drug and alcohol tests imposed in a statistically random and unpredictable manner. The discussion of § 26.67 in this document compares the random drug and alcohol testing requirements for initial authorization in this rule to the requirements in the former rule.

Section 26.55(b) of the final rule mandates that the licensee or other entity must meet the requirements in § 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 another licensee or other entity has not previously evaluated.

Section 26.57 Authorization update.

The NRC has added § 26.57 to the final rule, which defines 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 requirements for granting an authorization update are less stringent than the requirements for granting initial authorization. The requirements are less stringent because (1) the individual who is applying for an authorization update will have a more recent history of successful performance within the industry, and (2) the licensee or other entity will 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 final rule. However, the requirements in the final rule for an authorization update focus on gathering and evaluating information from the interruption period because the licensee or other entity will not have information about the individual's activities during the period of the interruption. For example, in the case of an individual whose last period of authorization ended 2 years ago, the licensee or other entity will 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 will focus on gathering information about the individual's activities within those 13 months.

Section 26.57(a) of the final rule, like § 26.55(a), requires the licensee or other entity before granting authorization to ensure that:

(1) A self-disclosure has been obtained and reviewed under the applicable requirements of § 26.61;

(2) A suitable inquiry has been completed under the applicable requirements of § 26.63;

(3) The individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65; and

(4) The individual has been subject to random drug and alcohol testing under the applicable requirements of § 26.67.

However, § 26.61(b)(3)(iii) and (c)(3) limits the period of time to be addressed in the self-disclosure and employment history to the interruption period. 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, § 26.63(f)(2) provides that the suitable inquiry for an authorization update must cover the interruption period. The final rule requires the self-disclosure, employment history, and suitable inquiry to address only the interruption period because the licensee or other entity may obtain information from earlier periods in the individual's history

from the licensee or other entity who had last granted authorization to the individual.

The NRC has added § 26.57(b) 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 under § 26.69.

Section 26.59 Authorization reinstatement.

The NRC has added § 26.59 to the final rule, which establishes 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.

One category of authorization reinstatement requirements applies to individuals whose authorization has been interrupted for more than 30 days but no more than 365 days in § 26.59(a), and the other to individuals whose authorization has been interrupted for 30 or fewer days in § 26.59(c). The steps for reinstating an individual's authorization after an interruption of 365 or fewer days are less stringent than those required for initial authorization or an authorization update because these individuals will have a recent, positive record within the industry and pose little risk to public health and safety or the common defense and security.

The requirements that are related to an individual whose authorization has been interrupted for more than 30 days but no more than 365 days are more extensive than the requirements for granting authorization to an individual whose authorization has been interrupted for 30 or fewer days. The requirements for the 31–365-day category are consistent with those contained in the access authorization orders issued by the NRC to nuclear power plant licensees dated January 7, 2003. However, the requirements for individuals whose authorization has been interrupted for 30 or fewer days are more stringent than those contained in those orders. 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 this amendment, licensees and other entities are also required to subject the individual to the possibility of selection for pre-access testing under § 26.65(e) [Authorization reinstatement after an interruption of 30 or fewer days]. The NRC has determined that this additional requirement is necessary to meet the final rule's performance objective of providing reasonable assurance that individuals are trustworthy and reliable 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, § 26.59(a)(1) requires the licensee or other entity to ensure that a self-disclosure and employment history has been obtained and reviewed in order to reinstate authorization. Consistent with the requirements for authorization updates in § 26.57, the final rule in § 26.61(b)(3)(iii) and (c)(3) limits 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 is unnecessary because the granting licensee or other entity will have access to information about the individual from the licensee or other entity who recently terminated the individual's authorization.

Section 26.59(a)(2) permits the licensee or other entity to reinstate an individual's authorization without first ensuring that a suitable inquiry has been completed, in contrast to the requirements for an initial authorization and an authorization update. The final rule permits this because these individuals will have a recent, positive record within the industry and pose little risk to public health and safety or the common defense and security. As is required for an authorization update, this provision limits the period of time to be addressed by the suitable inquiry to the interruption period in § 26.63(f)(3). However, this provision requires licensees and other entities to ensure that the suitable inquiry is completed within 5 business days after reinstating the individual's authorization. If the suitable inquiry is not completed within the 5-day

period, the licensee or other entity can maintain the individual's authorization for up to 10 business days following the day 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 10 business days, the rule requires the licensee or other entity to administratively withdraw the individual's authorization until the suitable inquiry is completed.

Section 26.59(a)(3) requires the licensee or other entity to ensure that the individual whose authorization has been interrupted for 31–365 days has been subject to pre-access drug and alcohol testing, and § 26.59(a)(4) requires the licensee or other entity to ensure that the individual whose authorization has been interrupted for 31–365 days is subject to random testing. Section 26.65(d) [Authorization reinstatement after an interruption of more than 30 days] establishes pre-access drug and alcohol testing requirements for authorization reinstatements. Section 26.67 [Random drug and alcohol testing of individuals who have applied for authorization] specifies the requirements for the random testing of individuals who are applying for an authorization reinstatement.

The NRC has added § 26.59(b) to the final rule to ensure that any administrative withdrawal of authorization required under § 26.59(a)(2) is not reported or recorded as an unfavorable termination of authorization until the suitable inquiry is completed and it indicates that authorization should not be granted. This provision ensures that a temporary administrative withdrawal of authorization caused by a licensee's or other entity's delay in completing the suitable inquiry is not treated as an unfavorable termination caused by an FFD violation. The final rule specifies that the individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information. With respect to the proposed rule, the final rule clarifies that the individual is required to disclose the administrative action if the individual's authorization was subsequently denied or terminated unfavorably. The NRC has made this change to the proposed rule in

recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking 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 26.59(b) is necessary to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) 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.

Section 26.59(c) of the final rule establishes authorization requirements for individuals whose authorization has been interrupted for 30 or fewer days. Section 26.59(c)(1) requires the licensee or other entity to ensure that a self-disclosure has been obtained and reviewed with certain exceptions that are specified in § 26.61 [Self-disclosure and employment history]. The licensee or other entity is permitted to forego conducting a suitable inquiry for individuals whose authorization has been interrupted for such a short period. Section 26.59(c)(2) permits 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. However, pre-access testing may be required under § 26.65(e) for individuals whose authorization has been interrupted for 6 to 30 days. Sections 26.61 and 26.65 specify the exceptions to the self-disclosure and pre-access testing requirements in this provision, respectively.

26.61 Self-disclosure and employment history.

The NRC has added § 26.61 to the final rule to replace former § 26.27(a)(1) for the reasons discussed in Section IV.C. The final rule replaces the term "written statement" in the former rule with the phrase "self-disclosure and employment history" to more accurately characterize the requirement. The NRC has made this change to meet Goal 6 of this

rulemaking to improve clarity in the language of the rule.

The NRC has added § 26.61(a) to the final rule to require licensees and other entities to ensure that a written self-disclosure and employment history has been obtained from every applicant before granting authorization to the individual, except in two circumstances, as follows.

Section 26.61(a)(1) permits 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 has been subject to a behavioral observation and arrest-reporting program that meets the requirements of this part throughout the time the individual's authorization was interrupted.

The information to be obtained from the self-disclosure and employment history is unnecessary in these circumstances because it will already be available to the granting licensee or other entity from the FFD 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 is redundant and imposes an unnecessary burden.

Section 26.61(a)(2) permits 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 is unnecessary in this case because the final rule does not require licensees or other entities to conduct a suitable inquiry for individuals who have had such a short break in authorization.

The NRC has added § 26.61(b) to the final rule to specify the required content of the written self-disclosure. Affirmative responses to any of the questions in § 26.61(b)(1) are

considered potentially disqualifying FFD information, as defined in § 26.5 [Definitions]. The final rule expands the scope of the questions to be asked from those required in former § 26.27(a)(1) in order to provide greater assurance that individuals will disclose information indicating an active substance abuse problem or an increased risk of recidivism into an active substance abuse problem after treatment. Former § 26.27(a)(2) required information about whether the applicant "tested positive for drugs or use of alcohol that resulted in on-duty impairment." Section 26.61(b)(1) requires 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 former § 26.27(a)(2) and § 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.

The NRC has added § 26.61(b)(2) to the final rule to require the applicant to disclose the circumstances surrounding any potentially disqualifying FFD information and the resolution of the matter. For example, § 26.61(b)(1) requires an applicant to report an arrest on drug-related charges, while § 26.61(b)(2) requires the applicant to report the outcome of the arrest (e.g., charges, a conviction, a finding of not guilty, the dropping of the charges).

Section 26.61(b)(3) defines the time period that the self-disclosure must address. The final rule establishes a time limit on the number of years in the past for which an individual is 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 post-treatment recidivism (i.e., relapse) rates decrease after 3 years of no further substance abuse, and a larger decrease occurs in the recidivism rate after 5 years. If the applicant discloses no indicators of a substance abuse problem within the past 5

years (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 § 26.55) is not required to disclose earlier events related to substance abuse. For applicants who held authorization within the past 3 years, the self-disclosure addresses only the time interval after the individual's last period of authorization ended. However, the licensee or other entity shall obtain further information about the applicant over the past 5 years by reviewing the information made available by licensees or other entities who granted authorization to the applicant in the past. This includes information developed as part of previous suitable inquiries (see § 26.63) as well as information from the period(s) during which the individual was subject to other FFD programs.

Section 26.61(c) in the final rule modifies this provision as proposed. The proposed rule specified that applicants must provide information about current and past employers, which the licensee or other entity then uses for the suitable inquiry if a suitable inquiry is required under § 26.63 [Suitable inquiry]. However, the final rule requires the individual to provide a list of employers to include the employer by whom he or she claims to have been employed on the day before he or she completes the employment history. The agency has also made this change in § 26.63(c). The NRC has made this change in response to a public comment, which stated that a licensee or other entity has the ability to ensure that a suitable inquiry has been conducted only of those employers that are listed in the self-disclosure or employment history. The NRC believes that this revision provides more specificity in cases when an individual's current employer changes after he or she submits the self-disclosure. This change is consistent with Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

The NRC has moved the provision in proposed § 26.61(d) to § 26.53(i)(2) of the final rule to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.63 Suitable inquiry.

The NRC has added § 26.63 to the final rule. This section amends former § 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 former § 26.3 [Definitions]. The former rule defined 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 NRC intends that the changes to the former requirements 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; increase the consistency in implementing suitable inquiries among FFD programs by providing more detailed requirements, also as discussed in Section IV.C; and improve Part 26 by eliminating or modifying unnecessary requirements, which is Goal 5 of this rulemaking.

For all authorization categories, the suitable inquiry required by the final rule is more thorough than previous industry practices to increase the likelihood that any potentially disqualifying FFD information is identified and provide reasonable 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 NRC has reduced the period of time addressed in the suitable inquiry from the past 5 years in every case, to the past 3 years or fewer, depending on how recently the applicant held authorization. If potentially disqualifying FFD information within the past 5 years is identified regarding an

applicant and a previous licensee or other entity has not addressed and favorably resolved it, the suitable inquiry requirements are more extensive, as described in § 26.69 [Authorization with potentially disqualifying fitness-for-duty information].

The NRC has added § 26.63(a) to the final rule to require licensees and other entities to ensure that a suitable inquiry has been conducted to verify the information provided by the applicant in the self-disclosure and employment history obtained under § 26.61 and to determine if additional potentially disqualifying FFD information is available regarding the applicant. The provision also establishes the circumstances in which a licensee or other entity is permitted to forego the suitable inquiry in order to grant authorization to individuals. A licensee or other entity is permitted to forego the suitable inquiry if the individual previously held authorization under Part 26, his or her last period of authorization was terminated favorably, and 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 is unnecessary in these circumstances because it will 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.

The final rule adds § 26.63(b) to the final rule to permit licensees and other entities to rely on suitable inquiry information that was gathered by previous licensees and other entities who are subject to this subpart. This provision reduces 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 provision also permits licensees and other entities to accept the results of 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 under the same requirements

in another Part 26 program. The NRC has made this change to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

With respect to the proposed rule, the final rule adds a cross-reference to § 26.189 [Determination of fitness] in § 26.63(b) to specify that licensees and other entities may only rely on determinations of fitness that were conducted under § 26.189. This change is necessary because the licensees and other entities specified in § 26.3(c) have greater latitude in conducting fitness evaluations under Subpart K [FFD Programs for Construction] than is permitted under § 26.189. However, as discussed with respect to § 26.53(f), a licensee or other entity who is subject to this subpart is permitted to rely on a determination of fitness conducted under a Subpart K program if the determination of fitness met the requirements in § 26.189.

The NRC has added § 26.63(c) to the final rule, which specifies requirements for conducting suitable inquiries. Licensees and other entities shall ensure that a "best effort" is demonstrated 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 the company employed an individual, 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 requires licensees and other entities to ensure that suitable inquiry information is sought 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 paragraph is consistent with the "best-efforts basis" in former § 26.27(a)(2). However, the final rule provides more detailed requirements in response to questions that the

NRC has received from licensees about implementing a suitable inquiry on a “best effort” basis after Part 26 was first promulgated. Also, the final rule modifies the proposed rule to more clearly specify which employers must be questioned as discussed with respect to § 26.61(c).

The NRC has added § 26.63(c)(1) to the final rule, which specifies the type of information that the licensee or other entity must seek from employers regarding the applicant for authorization. This provision requires 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 requirement to obtain this information is 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.

Section 26.63(c)(2) specifies the type of information that licensees and other entities must seek when an applicant’s claimed periods of employment include military service. The NRC has added this requirement 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.

The NRC has added § 26.63(c)(3) to the final rule to 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 are 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 § 26.63(c)(3), the provision requires 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 is not 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 final rule prohibits 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 provision permits 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. With respect to the proposed rule, the final rule clarifies that the licensee shall evaluate and document the response if it is received. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking 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 alternative methods of meeting the suitable inquiry requirement are necessary because some employers are unwilling or unable to provide suitable inquiry information.

The NRC has added § 26.63(d) to the final rule, which requires licensees and other entities to share suitable inquiry information that they have collected when contacted by another licensee or entity who has a release signed by the applicant for authorization that permits the sharing of that information. This provision restates the permission to release suitable inquiry information in former § 26.29(b) as a requirement that licensees and other entities must share the information necessary to conduct the suitable inquiry. With respect to the proposed rule, the final rule clarifies this provision as a result of a public comment that disagreed with the use of the word “presentation” in the proposed provision. The NRC concurred with the comment and believes that current practices in the industry allow for verification of a signed release without the licensee presenting the actual document. Therefore, the NRC has made this

change to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule. Also, the final rule expands the list of the types of information that licensees and other entities must make available and on which the denial or unfavorable determination of authorization was based. The NRC has made this change because after publishing the proposed rule, it recognized the need for additional clarity to reflect the NRC's intent beyond what the proposed rule contained.

Section 26.63(d) clarifies that the information must also be released to C/Vs who have licensee-approved FFD programs when the C/V has obtained the required signed release from the applicant. This clarification is necessary because some licensees have misinterpreted former § 26.29(b) as prohibiting the release of suitable inquiry information to C/Vs who have licensee-approved FFD programs. The provision also imposes the requirement on licensees and other entities who may be implementing an FFD program under Subpart K [FFD programs for construction] of this part. The NRC has made this change for consistency with the new requirements in Subpart K of this rule and to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has moved the portion of proposed § 26.63(d) that specified that a failure of an individual to authorize the release of information for the suitable inquiry is sufficiency cause for a denial of authorization to § 26.53(i)(1) of the final rule. The NRC has made this change to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.63(e) to the final rule to permit licensees and other entities to use electronic means to obtain the suitable inquiry information. This permission is 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 paragraph also adds cross-references to the applicable records retention requirements in § 26.711 [General provisions] and § 26.713 [Recordkeeping requirements for licensees and other entities] in

Subpart N [Recordkeeping and Reporting Requirements] to the final rule to ensure that licensees and other entities are aware of the applicability of these requirements to the suitable inquiry information obtained electronically. These changes are consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.63(f) to the final rule, which specifies the period(s) of time that the suitable inquiry must address for applicants for initial authorization, authorization update, and authorization reinstatement. The final rule specifies that the suitable inquiry requirements in this provision apply only to those individuals about whom no potentially disqualifying FFD information is known at the time the suitable inquiry is initiated. The NRC added this provision to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

Section 26.63(f) specifies the following additional requirements for conducting the suitable inquiry for these authorization categories. Section 26.63(f)(1) [Initial authorization] requires licensees and other entities to conduct a suitable inquiry to address the 3-year period preceding the date the individual applies for authorization. The NRC has reduced the period of time that the suitable inquiry must address for applicants for initial authorization who do not disclose any potentially disqualifying FFD information. The NRC has reduced the period of time to be addressed in the suitable inquiry from 5 years in the former regulation to 3 years to better focus the suitably inquiry on identifying indicators of an active substance abuse problem or an increased risk of recidivism following treatment. If an applicant for initial authorization discloses no potentially disqualifying FFD information 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 be unlikely to provide useful data and imposes an unnecessary burden. Industry experience has shown that employers are often reluctant to disclose adverse information to other private employers about former employees. Also, 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 final rule increases the thoroughness of the suitable inquiry over the past 3 years.

Section 26.63(f)(1) requires the licensee or other entity to ensure that the suitable inquiry has been conducted with every employer by whom the applicant claims to have been employed within the past year. This requirement leads to a more rigorous suitable inquiry than was common industry practice before the issuance of the January 7, 2003, access authorization orders, which imposed additional compensatory measures related to access authorization. The purpose of contacting every employer is to ensure that the licensee or other entity sought information related to any active substance abuse problem. For the earlier years of the suitable inquiry period, the provision requires the licensee or other entity to ensure that the suitable inquiry has been conducted with every employer by whom the applicant claims to have been employed the longest within each calendar month. Contacting these employers increases the likelihood that the employers would have knowledge of the applicant and may provide more useful information than contacting employers who employed the applicant only briefly.

The NRC has added § 26.63(f)(2) [Authorization update] to the final rule, which specifies 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 paragraph requires the licensee or other entity to ensure that the suitable inquiry has been conducted in the same manner as described in § 26.63(f)(1). However, for an authorization update, the suitable inquiry addresses only the period during which the individual's authorization was interrupted, rather than the full 3 years that is required for initial authorization. A 3-year period for the suitable inquiry is unnecessary for these individuals because the licensee or other entity will 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.

Section 26.63(f)(3) [Authorization reinstatement after an interruption of more than 30 days] specifies 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 final rule requires licensees and other entities to ensure that the suitable inquiry has been conducted with the employer by whom the applicant claims to have been employed the longest in each calendar month of the interruption. This provision does not require licensees and other entities to ensure that every employer by whom the individual claimed to have been employed during the interruption is contacted for the reasons discussed with respect to § 26.59(a)(2). Because these individuals have had only a short break in authorization, a sampling of employers from the interruption period is sufficient to determine if any indications exist that the individual has 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 § 26.63(f)(1) through (f)(3) are 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.

Section 26.65 of the final rule amends former § 26.24(a)(1). The former provision required 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 final rule amends the former pre-access drug and alcohol testing requirement for individuals who are seeking authorization under Part 26 to strengthen the effectiveness of FFD programs.

The NRC has added § 26.65(a) [Purpose] to the final rule to describe the purpose of the section and identify the individuals to whom the requirements in the section apply. The pre-access testing requirements in this section cover applicants for authorization 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 about whom no potentially disqualifying FFD information has been discovered or disclosed that was not reviewed and favorably resolved by another licensee or entity who is subject to Subpart C. 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, are contained in § 26.69 [Authorization with potentially disqualifying fitness-for-duty information].

The NRC has added § 26.65(b) [Accepting tests conducted within the past 30 days] to the final rule to permit licensees and other entities to forego pre-access testing of an individual who has negative results from drug and alcohol tests that were performed under 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 final rule permits 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 authorization is granted to the individual. A requirement for the licensee or other entity to conduct pre-access testing in these circumstances is redundant and unnecessary.

The NRC has added § 26.65(c) [Initial authorization and authorization update] to the final rule, which establishes pre-access testing requirements for individuals who are applying for

initial authorization and an authorization update. The final rule, with respect to the proposed rule, has added a specification that before granting initial authorization, any pre-access drug and alcohol tests must be conducted within the 30-day period preceding the day the licensee or other entity grants authorization to the individual. Under former § 26.24(a)(1), licensees and other entities were permitted to complete pre-access testing within the 60-day period before authorization is granted. The inclusion in the final rule of a shorter time period within which pre-access testing must be conducted, if required, increases 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 are performed. In addition, the decreased time period for pre-access testing increases the likelihood that recent drug use, particularly marijuana, is detected before the concentration of metabolites in an individual's body could decrease below the cutoff levels prescribed in the final rule. Also, the final rule's provision for a decreased time period within which pre-access testing must be performed provides greater assurance that individuals subject to this part are trustworthy and reliable, as demonstrated by the avoidance of substance abuse, as discussed with respect to § 26.23(a).

The final rule requires negative results from pre-access testing before the licensee or other entity grants authorization to the individual, except in the two circumstances described in § 26.65(c)(1) and (c)(2). Pre-access testing in these two circumstances is unnecessary because there is sufficient opportunity to detect substance abuse without the testing. In § 26.65(c)(1), licensees and other entities are 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 the individual's authorization was interrupted.

In proposed § 26.65(c)(2), licensees and other entities were permitted to forego pre-

access testing of an applicant who had negative results from Part 26 drug and alcohol tests that were performed within the past 30 days and who was subject to behavioral observation and arrest-reporting requirements during the time interval between the day the specimens were collected and the day the licensee or other entity grants authorization to the individual. However, the NRC received a public comment regarding this provision, which stated that licensees should be able to rely on drug and alcohol tests that were conducted before the individual applied for authorization if the individual has been subject to a behavioral observation and arrest-reporting program, and random drug and alcohol testing, during the time period following the drug and alcohol tests. The NRC agrees that pre-access testing within 30 days before authorization is granted is unnecessary in these circumstances and has removed reference to § 26.65(b) in this provision. This amendment clarifies that licensees may rely on drug and alcohol tests that were conducted at any time before the individual applied for authorization, provided that the individual has been subject to a random drug and alcohol testing program, a behavioral observation program, and an arrest-reporting program that meet the applicable requirements of this part. The NRC has made this change under Goal 5 of the rulemaking to improve the rule by eliminating or modifying unnecessary requirements.

The NRC has added § 26.65(d) [Authorization reinstatement after an interruption of more than 30 days] and (e) [Authorization reinstatement after an interruption of 30 or fewer days] to the final rule, which establish requirements for the pre-access testing of individuals who are applying for an authorization reinstatement. The requirements for pre-access testing of these individuals are less stringent than the requirements for initial authorization and an authorization update. The provision relaxes the pre-access testing requirements in former § 26.24(a)(1), which mandated that all applicants for authorization must be subject to pre-access testing within 60 days before granting authorization. Less stringent pre-access testing requirements are appropriate because these individuals have met the rigorous criteria for initial

authorization, established a recent record of successfully maintaining authorization under Part 26, and had only a short break in authorization.

Section 26.65(d) of the final rule specifies pre-access testing requirements for individuals whose authorization has been interrupted for more than 30 days but no more than 1 year. Section 26.65(d)(1)(i) requires the licensee or other entity to administer an alcohol test and collect a urine specimen for drug testing. The final rule, with respect to the proposed rule, clarifies that before granting initial authorization, any required pre-access drug and alcohol tests must be conducted within the 30-day period preceding the day the licensee or other entity grants authorization to the individual. The licensee or other entity is permitted to reinstate the individual's authorization if the alcohol test results are negative before the drug test results are available. Section 26.65(d)(1)(ii) permits the licensee or other entity to maintain the individual's authorization for 5 business days after reinstatement without receiving the drug test results. However, if the licensee or other entity does not receive negative drug test results within 5 business days of reinstating the individual's authorization, the final rule requires the licensee or other entity to administratively withdraw the individual's authorization until negative drug test results are received. These requirements 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 provisions do not unduly delay authorization reinstatement because these individuals' recent successful histories of maintaining authorization under Part 26 indicate that they are at low risk of engaging in substance abuse.

Section 26.65(d)(2) permits licensees and other entities to forego pre-access testing of these applicants for reinstatement in the circumstances discussed with respect to § 26.65(c)(1) and (c)(2). The discussion with regard to § 26.65(c)(2) also specifies the reasons for the changes from the proposed rule in § 26.65(d)(2)(ii).

The NRC has added § 26.65(e)(1) to the final rule to permit licensees and other entities to forego pre-access testing of applicants whose authorization has been interrupted for 5 or fewer days. This provision is consistent with current licensee practices and recommendations regarding short breaks in authorization in NUREG-1385 and other access authorization requirements. The final rule also has moved the provisions from paragraph (e)(3) of the proposed rule into this paragraph of the final rule to improve clarity in the organization of the final rule, consistent with Goal 3 of the rulemaking. This provision permits licensees and other entities also to forego subjecting an individual to the possibility of selection for pre-access testing if the applicant has 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. The NRC believes that being subject to these program elements during the interruption period is sufficient to deter substance abuse and provide assurance that substance abuse would be detected. Section 26.65 enhances 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.

Section 26.65(e)(2) of the final rule requires licensees and other entities to subject applicants whose authorization has been interrupted for 6 to 30 days to the possibility of selection for pre-access testing in order to deter any potential for substance abuse. However, this provision specifies that the licensee or other entity may forego subjecting an individual to the possibility of being selected for pre-access testing if the applicant has 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.

Section 26.65(e)(2)(i) requires 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

probability approximates the likelihood that individuals who are subject to random testing at the 50-percent annual testing rate in § 26.31(d)(2)(vii) are selected for testing at some point within a 30-day period. Section 26.65(e)(2)(ii) clarifies that if an applicant is not selected for pre-access testing under the preceding section, the licensee or other entity is not required to perform a pre-access test. Section 26.65(e)(2)(iii)(A) and (B) specifies requirements for conducting the pre-access testing if an individual is selected for testing under § 26.65(e)(2)(i). The licensee or other entity shall 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 final rule requires that the licensee or other entity must receive negative drug test results within 5 business days after reinstatement or administratively withdraw the individual's authorization until negative drug test results are received.

The NRC has deleted from the final rule § 26.65(f) [Time period for testing] of the proposed rule. The proposed provision mandated that specimens that are collected for any pre-access testing required in this section must be collected within the 30-day period preceding the day the licensee grants authorization to an individual. The NRC received a public comment that stated that licensees currently conduct pre-access drug and alcohol testing within the 30-day period preceding the date the licensee grants authorization and that proposed § 26.65(f) only requires licensees to collect a sample in this timeframe. The NRC agrees with the comments and, therefore, has deleted this provision from the final rule to increase efficiency, consistent with Goal 5 of the rulemaking to eliminate unnecessary requirements. However, the NRC has added requirements to § 26.65(c) and (d)(1)(i) to specify that any pre-access testing required in this section must be conducted within the 30-day period preceding the day upon which the licensee grants authorization to an individual, consistent with the proposed rule's

intent. Under former § 26.24(a)(1), licensees and other entities were permitted to complete pre-access testing within the 60-day period before authorization is granted. The reason why the final rule shortens this time period to 30 days is discussed with respect to § 26.65(c).

The NRC has added § 26.65(f) [Administrative withdrawal of authorization] (changed from § 26.65(g) in the proposed rule because of renumbering) to the final rule 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 paragraphs (d)(1)(ii) or (e)(2)(iii)(B) of this section. The time a licensee or other entity receives drug test results is not under the applicant's control and does not reflect on 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 is inappropriate, except if the individual's authorization was subsequently denied or terminated unfavorably by a licensee or entity. However, if the drug test results are positive, adulterated, or substituted and the licensee or other entity terminates the individual's authorization for cause, the termination is then recorded as unfavorable. However, with respect to the proposed rule, the final rule adds a clarification that the individual is required to disclose administrative action if the individual's authorization was subsequently denied or terminated unfavorably. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking 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.

The NRC has added § 26.65(g) [Sanctions] (changed from § 26.65(h) in the proposed rule because of renumbering) to the final rule, which specifies the minimum sanctions to be imposed on an individual whose pre-access test results the MRO confirms as an FFD policy violation. Section 26.65(g)(1) and (g)(2) contains cross-references to the relevant sanctions specified in Subpart D [Management Actions and Sanctions To Be Imposed] to clarify that those sanctions 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 is required to impose the sanction for an attempt to subvert the testing process (i.e., permanent denial of authorization) in § 26.75(b).

The NRC has added § 26.65(g)(3) to the final rule to permit licensees and other entities to grant authorization to an individual whose confirmed positive, adulterated, or substituted test result is a first drug- or alcohol-related violation under a Part 26 program, consistent with former § 26.27(b)(2). However, the final rule permits authorization to be granted only under the stringent requirements contained in § 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.

The NRC has added § 26.67 to the final rule, which extends former random testing requirements to individuals who have applied for authorization under Part 26 but who have not yet been granted authorization. The NRC has added the requirements in this section to the access authorization requirements that were established by orders to nuclear power plant licensees dated January 7, 2003, to enhance the effectiveness of FFD programs by increasing the likelihood that substance abuse will be detected before authorization is granted and to deter the potential for substance abuse among applicants. Therefore, the NRC has made these

changes to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.67(a) to the final rule, which requires licensees and other entities to conduct random testing of applicants under the requirements of § 26.31(d)(2). The licensee or other entity must add applicants for authorization 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 is subject to random testing beginning when the licensee or other entity collects the specimens for any required pre-access test and continues thereafter, if the licensee or other entity grants authorization to the individual.

Licensees and other entities are permitted to forego random testing of applicants in the two circumstances described in § 26.67(a)(1) and (a)(2). Section 26.67(a)(1) permits 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. Section 26.67(a)(2) addresses the circumstance described in § 26.65(b), in which the licensee or other entity is permitted to meet pre-access testing requirements by relying on negative test results from specimens collected under another Part 26 program within 30 days before granting authorization to the individual. Under § 26.67(a)(2), the licensee or other entity shall 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 formal actions may include, but are not limited to, the time when 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 on the licensee's FFD and access authorization program procedures, whether the applicant's FFD training is up-to-date, and other factors. These considerations make it impractical to establish a single point in the authorization process established in the rule when random testing must begin. Therefore, the provision requires 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 does not define a specific formal action that would initiate random testing of applicants in all cases.

The NRC has added § 26.67(b) to the final rule, which permits 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. The final rule does not require the testing to be completed before the licensee or other entity grants authorization to the individual because the primary purpose of randomly testing applicants is to deter substance abuse rather than to provide information for the authorization decision. Pre-access testing provides the necessary information for authorization decision making.

Section 26.67(c) of the final rule cross-references the minimum sanctions to be imposed on an individual whose drug or alcohol results from random testing are confirmed as positive, adulterated, or substituted. The final rule also makes a minor language clarification to the proposed rule by modifying the term "non-negative"of this section. Section 26.67(c)(1) and (c)(2) refers to the relevant sanctions specified in Subpart D [Management Actions and Sanctions To Be Imposed]. Section 26.67(c)(3) continues to permit licensees and other entities

to grant authorization to an individual whose confirmed positive, adulterated, or substituted test result is a first drug- or alcohol-related violation under a Part 26 program, consistent with former § 26.27(b)(2). However, the final rule permits authorization to be granted only under the stringent requirements contained in § 26.69 [Authorization with potentially disqualifying fitness-for-duty information].

Section 26.69 Authorization with potentially disqualifying fitness-for-duty information.

The NRC adds § 26.69 to the final rule to replace and clarify the requirements contained in former § 26.27(b)(4). Former § 26.27(b)(4) established 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 more years under the former rule. Consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule, this section of the final rule addresses problems that have arisen in implementing the former rule and clarifies the NRC's intent with respect to several situations that the former rule did not address.

The NRC has added § 26.69(a) [Purpose] to the final rule to describe the purpose of the section and the applicants who are subject to these requirements. The provision requires 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 the individual through any means and a previous licensee or other entity has not assessed and favorably resolved the information. Section § 26.63(b) permits licensees and other entities to rely on the results of determinations of fitness that previous licensees or other entities conducted, 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 by another FFD program under this subpart, licensees and other entities must implement the requirements contained in this section.

Section 26.69(a) also revises the language contained in former § 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, are not required to implement these requirements. At the public meetings discussed in Section I.D, stakeholders noted that some individuals have misinterpreted the former 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 former and final rules assign the responsibility for making authorization decisions to the licensee or other entity. Therefore, the paragraph clarifies 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."

The NRC has added § 26.69(b) [Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization] to the final rule 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 was previously terminated unfavorably or denied for 5 years. The requirements in this section 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 § 26.75(e)(1) (The NRC has moved the provisions in former § 26.26(b)(2) to § 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 § 26.75(c), (d), (e)(2), or (f).

This provision replaces and strengthens the requirements contained in former § 26.27(b)(2) and expands them to address confirmed positive alcohol test results, which were excluded from this process in former § 26.27(b)(5). The paragraph includes confirmed positive alcohol test results for the reasons discussed with respect to § 26.75(e).

The NRC has retained the language of the proposed rule to state that the licensee or other entity shall perform the activities listed in paragraphs (b)(1) through (b)(6) of this section. In the situations presented in this section, the NRC believes that the licensees or other entities will likely conduct these tasks themselves because another licensee has not reviewed and resolved the individual's situation. Therefore, the licensees will have to collect more original data about the individual, rather than relying on that collected by another licensee. However, by retaining the language of the proposed rule in this section, the NRC does not intend to require that the licensees or other entities must conduct these tasks themselves in these situations. The NRC maintains that the licensee may rely on information collected by others to meet the requirements of § 26.69 if that is the most reasonable way to proceed. For example, if the licensee or other entity uses a background screening company, they would most likely continue to have the company perform the employment history required in this section.

Section 26.69(b)(1) requires the licensee or other entity to obtain and review a self-disclosure and employment history from the applicant to verify that it does not contain any previously undisclosed potentially disqualifying FFD information. The final rule has added “employment history,” with respect to the proposed rule, to state the intent that both a self-disclosure and employment history shall be reviewed. When an individual’s last period of

authorization was terminated unfavorably or denied, licensees and other entities are not permitted to forego obtaining a self-disclosure and employment history under any circumstances because it is important to review the individual's activities during the interruption period. The period of time the self-disclosure must address is the shorter of either the past 5 years or the intervening period after the individual last held authorization.

Section 26.69(b)(2) increases the scope of the suitable inquiry 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 employment history. The final rule replaces "self-disclosure" in the proposed rule with "employment history" to clarify that the time period covered is that which the employment history addresses. This extensive suitable inquiry is necessary to determine if any indications exist that the individual has continued to engage in substance abuse. The final rule also requires 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 are not 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. The SAE uses this information to assess the individual's fitness and the licensee's or other entity's reviewing official uses it to determine whether authorization is warranted.

Section § 26.69(b)(3) applies only to individuals whose authorization was denied for 5 years under the former rule or under § 26.75(c), (d), (e)(2), or (f) of the final rule. The paragraph requires 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 requirement is consistent with the portion of former § 26.27(b)(4) that required licensees to obtain "satisfactory medical assurance that the person has abstained from drugs for at least 3

years." However, the final rule extends the requirement to 5 years to ensure that such an individual is at the lowest risk of recidivism into an active substance abuse problem before the licensee or other entity grants authorization to the individual.

Section 26.69(b)(4) amends the requirement in former § 26.27(b)(2). The former provision mandated 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 final rule makes several changes to the former provision. First, the final rule replaces the term "management and medical assurance of fitness" which was used in former § 26.27(b)(2) and (b)(4), with the term "determination of fitness" to improve the accuracy of the language in the final rule. The final rule does not use "management" because the licensee's or other entity's reviewing official [see the discussion of § 26.69(c)(3) and the definition of "reviewing official" in § 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 final rule permits professionals other than a licensed physician to conduct a determination of fitness, for the reasons discussed with respect to § 26.189 [Determination of fitness]. The NRC has made these change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Consistent with the intent of the former requirement, the provision requires the licensee or other entity to ensure that an SAE has conducted a determination of fitness, as defined in § 26.189 [Determination of fitness], as part of the authorization decision. Section 26.187 [Substance abuse expert] requires that an SAE must perform determinations of fitness that are conducted for authorization decisions. Section 26.187 also defines the role, responsibilities, and required qualifications of an SAE. Therefore, § 26.69(b)(4) requires that the individual must be referred to an SAE for a determination of fitness. However, the final rule does not require the SAE to be an EAP employee. Permitting licensees and other entities to rely on a

professional who meets the required qualifications for an SAE rather than only on EAP personnel, more appropriately focuses this requirement on ensuring that the professional who performs the assessment and treatment planning is qualified, rather than on the professional's organizational affiliation. The NRC received a comment requesting that the rule rely on a Substance Abuse Professional (SAP) to meet the requirement of this section. The NRC acknowledges that the SAP training and credentialing process emphasizes knowledge about the SAP role in programs under 10 CFR Part 40, "Domestic Licensing of Source Material." However, although an SAP under Part 40 meets many of the criteria established in the rule, thorough knowledge of Part 26 requirements is also necessary. Therefore, the NRC has not modified the proposed provision in the final rule.

Section 26.69(b)(4)(i) through (b)(4)(iii) replaces and strengthens the requirement in former § 26.27(b)(2). The former provision stated that "any rehabilitation program deemed appropriate must be initiated during such suspension period." The final rule requires that the individual must be in compliance with or have successfully completed treatment and follow-up testing 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.

The NRC has added § 26.69(b)(5) to the final rule 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 provision requires negative results from an alcohol test performed within 10 business days before authorization is granted. Similarly, the provision requires negative results from a urine specimen that was collected under direct observation for drug testing within 10 business days before authorization is granted. The provision prohibits 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. The MRO may then determine whether the drug test results indicate that the individual has not engaged in any further drug abuse [see the discussion of § 26.69(f)]. Completing drug and alcohol testing within 10 business days before granting authorization rather than the 30 days that is permitted in § 26.65 for the other authorization categories provides evidence that the individual has abstained from abusing proscribed substances during the interruption period and that the individual is 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 former § 26.27(b)(2) and retained in § 26.75(e)(1). Requiring direct observation of the urine specimen collection is necessary to provide added assurance that the specimen is valid and yields accurate drug test results.

Section 26.69(b)(6) applies 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 provision replaces the third sentence of former § 26.27(b)(4). This sentence established requirements and a schedule for followup drug and alcohol testing for an individual whose authorization was denied for 3 years under the former rule. The final rule applies the requirement for followup testing to individuals who have had a first confirmed positive test result for drugs or alcohol. This requirement provides greater deterrence of further drug and alcohol use than former § 26.27(b)(4), which required 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 provides higher assurance that individuals who are subject to this part are trustworthy, reliable, and fit for duty.

Section 26.69(b)(6) amends the former 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 rule requires licensees and other entities to ensure that the individual is subject to unannounced testing at least 15 times within the 3-year period and to verify that the individual's test results are negative. Either random or followup tests, which are both unannounced, may be used to meet this final requirement. The final rule requires licensees and other entities to distribute the unannounced tests over the 3-year period, with at least one unannounced test conducted each quarter.

The NRC has added § 26.69(b)(6)(i) through (b)(6)(iii) to the final rule to address circumstances when an individual is not continuously subject to a Part 26 program during the 3 years following the restoration of authorization. Section 26.69(b)(6)(i) requires 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. Section 26.69(b)(6)(ii) permits 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 final 15-test requirement. Section 26.69(b)(6)(iii) permits 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 because of brief and infrequent periods of authorization. The revision of these requirements increase the flexibility with which licensees and other entities may implement followup testing, but retains the former effectiveness of followup testing in detecting and deterring substance abuse.

The NRC has added § 26.69(b)(7) to the final rule, which requires 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 the restoration of the individual's authorization indicate no

further drug or alcohol abuse. The provision does 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 § 26.185(o), is required to determine whether the results indicate new drug use or are consistent with results that are expected from the drug use that resulted in the previous confirmed positive test result. The rule adds this requirement in response to inconsistencies in the way some MROs have implemented former 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 change permits 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 § 26.75(e)(2).

The NRC has added § 26.69(c) [Granting authorization with other potentially disqualifying FFD information] to the final rule to establish requirements for granting authorization to an individual about whom potentially disqualifying FFD information is discovered or disclosed that was not a confirmed positive, adulterated, substituted, or invalid drug or alcohol test result or 5-year denial of authorization. For example, this type of potentially disqualifying FFD information may include, but is not limited to:

(1) A report of an arrest for an alcohol-related traffic violation;

(2) Information from the suitable inquiry that a previous private-sector employer

terminated an individual's employment 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.

This provision is necessary because the former rule did not address the authorization process in these circumstances and the NRC is aware that licensees and other entities have handled these circumstances inconsistently. Therefore, the final rule adds these requirements to establish the NRC's intent with respect to these circumstances and increase consistency between Part 26 programs.

The NRC has added a second sentence to § 26.69(c) in the final rule to clarify that if potentially disqualifying FFD information is obtained about an individual by any means, the licensee shall perform the activities in paragraphs (c)(1) through (c)(5) of this section before granting authorization to the individual. The NRC has made this change to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.69(c)(1) to the final rule, which requires the licensee or other entity to obtain and review the individual's self-disclosure and employment history. The final rule has added the term "employment history" to clarify that the licensee must obtain and review that in addition to the self-disclosure. The final rule also modifies the language of the proposed rule by eliminating reference to § 26.31(b)(3) and instead adding paragraphs (c)(1)(i) through (c)(1)(iii) to § 26.69 to specify exactly the time period that the self-disclosure and employment history must address. The NRC has made this change in response to a public comment suggesting that this provision needed clarification and to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

Section 26.69(c)(2) requires the licensee or other entity to conduct a suitable inquiry

with every employer for the period that the employment history addresses. In this section, the final rule deletes “self-disclosure” and replaces it with the phrase “employment history required under paragraph 26.63(a) through (e)” to clarify the time period addressed. If the potentially disqualifying FFD information was identified during the course of conducting a suitable inquiry under § 26.63(f) so that the suitable inquiry was partially completed, § 26.69(c)(2) requires 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 provision also requires that if the individual held authorization within the past 5 years, the licensee or entity shall 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. The final rule, with respect to the proposed rule, has added the phrase “if the individual held authorization within the past 5 years” to meet Goal 6 of the rulemaking to improve clarity in the language of the rule. This more complete suitable inquiry is 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.

The NRC has added § 26.69(c)(3) to the final rule, which uses the term “reviewing official” to refer to the employee who the licensee or other entity designates to make authorization decisions as discussed with respect to § 26.5 [Definitions]. This provision permits 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 provision also grants 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, § 26.69(c)(4) requires the licensee or other entity to implement the treatment and testing recommendations.

The NRC has added § 26.69(c)(5) to the final rule to require pre-access and random testing of the applicant for authorization. This provision requires 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, to provide evidence that the individual is avoiding substance abuse.

The NRC has added § 26.69(d) [Maintaining authorization with other potentially disqualifying FFD information] to the final rule, which establishes requirements for maintaining an individual's authorization when new potentially disqualifying FFD information is disclosed or discovered that was not a confirmed positive 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 are not required because the individual would not be applying for authorization. However, the provision requires the reviewing official to consider 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 provision mandates that the licensee or other entity must implement any treatment or testing requirements resulting from the determination of fitness. The NRC has added the provision because the former rule did not address maintaining an individual's authorization in these circumstances. Also, the NRC is aware that licensees and other entities have handled these circumstances inconsistently. Therefore, the final rule adds these requirements to establish the NRC's intent with respect to these circumstances and to increase consistency between Part 26 programs.

The NRC has added § 26.69(e) [Accepting followup testing and treatment from another

Part 26 program] to the final rule to establish continuity of care requirements for individuals who were subject to a followup testing and/or a 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.

Section 26.69(e)(1) requires the receiving licensee other entity to continue the testing and treatment plan to which the individual was subject under the previous FFD program. However, with respect to the proposed rule, the final rule clarifies that the licensee or other entity who imposed the treatment and/or followup testing plan shall ensure that information documenting the treatment and/or followup testing plan is identified to any subsequent licensee or other entity who seeks to grant authorization to the individual. The NRC has made this change to clarify the intent of the provision and in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking 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 26.69(e)(1) of the final rule also adds a specification that if it is impractical for the individual to comply with the treatment plan that was developed under another FFD program, the granting FFD program shall ensure that an SAE develops a comparable treatment plan. The NRC has made this change because it received a public comment stating that the proposed provision that required the licensee to assume responsibility for overseeing the continuation of treatment and follow-up testing for an employee who had a positive test result under another FFD program could be burdensome, especially if the individual is applying for authorization at a new site that makes it impossible to use the same treatment providers.

Section 26.69(e)(2) permits the receiving licensee or other entity to accept and rely on any followup testing that was completed while the individual was subject to the previous Part 26

program to determine 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, the granting licensee would then administer the final year of the followup testing. However, the licensee is not required to 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, this provision permits the receiving licensee or other entity to accept the previous determination of fitness and does not require the granting licensee to develop and implement an additional testing and treatment plan.

The NRC has added § 26.69(f) [Sanctions] to the final rule to clarify the minimum sanctions to be imposed on an individual who has confirmed positive, adulterated, or substituted drug and alcohol test results on any tests that may be required under this section. Section 26.69(f)(1) and (f)(2) cross-references the relevant sanctions specified in Subpart D [Management actions and Sanctions To Be Imposed] to establish that those sanctions apply to individuals about whom potentially disqualifying FFD information has been discovered or disclosed.

Section 26.71 Maintaining authorization.

The NRC has added § 26.71 [Maintaining authorization] to the final rule to state the requirements for maintaining authorization under this part and has adopted the provisions in this section as proposed without change. Section 26.71(a) of the final rule provides that individuals may maintain authorization under the conditions listed in § 26.71(a)(1) through (a)(4), as follows:

Section § 26.71(a)(1) establishes that an individual must comply with the licensee's or other entity's FFD policies to which the individual is subject. This requirement relates, although it does not refer to § 26.27 [Written policy and procedures] that requires 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 the policy. The final rule requires that all individuals who are subject to the FFD policy must have information on the expectations of them and the consequences that may result from a lack of adherence to the policy. Section 26.71 also requires that in order to maintain authorization, an individual must report any legal actions as defined in § 26.5 [Definitions]. Finally, although not explicitly specified in § 26.71(a)(1), § 26.33 [Behavioral observation] requires individuals to report any FFD concern to the personnel designated in the FFD policy.

Section 26.71(a)(2) establishes 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 § 26.31 [Drug and alcohol testing]. 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)). Section 26.31 also places certain responsibilities on individuals who are subject to the testing program. In particular, under § 26.31(d)(2)(iii), individuals who are selected for random testing are required to report to the collection site as soon as reasonably practicable after notification 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.

Section 26.71(a)(3) establishes 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 § 26.33 [Behavioral observation], is 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.

Section 26.71(a)(4) establishes that a condition for maintaining authorization is the individual's successful completion required of FFD training, according to the schedule in § 26.29(c). As specified in § 26.29(c)(1), the final rule requires the individual to complete training before the licensee or other entity grants initial authorization. Thereafter, as specified in § 26.29(c)(2), the rule requires individuals to complete refresher training or pass a comprehensive examination on a nominal 12-month frequency. Section 26.29(d) provides that licensees and other entities may accept the training of individuals who have been subject to another Part 26 program and have either had initial or refresher training or successfully passed a comprehensive examination within the past 12 months that meets the requirements of § 26.29.

Section 26.71(b) of the final rule requires a licensee or other entity to terminate an individual's authorization if the individual is not subject to an FFD program that meets the requirements of Part 26 for more than 30 (consecutive) days. The requirements of the paragraph permits 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 is not reasonably available for behavioral observation or to collect specimens for random drug and alcohol testing. The NRC has added this paragraph to the final rule in response to stakeholder requests, and it is 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 To Be Imposed

Throughout this subpart, the final rule makes minor clarifications to the proposed rule due to public comment, to accommodate conforming changes, and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. The final rule makes other substantive changes in §§ 26.73; 26.75(e)(1) and (h); and 26.77(b)(2) that are discussed with regard to those sections. Otherwise, the final rule has adopted the provisions in this section as proposed without change.

Section 26.73 Applicability.

The NRC has added § 26.73 to the final rule to describe the applicability of the subpart. The new § 26.73 specifies, by using applicable cross-references to §§ 26.3 [Scope] and 26.4 [FFD program applicability to categories of individuals], the licensees and other entities, as well as individuals, to whom the requirements of this subpart apply.

Section 26.75 Sanctions.

The first sentence of § 26.75(a) of the final rule introduces the purpose of the section, which is 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 paragraph restates the second sentence of former § 26.27(b). This sentence permits licensees and other entities to impose more stringent sanctions than those specified in the final rule. The final rule adds a cross-reference to paragraph (h) of this section, which establishes limits on the sanctions that licensees and other entities may impose for positive, adulterated, substituted, or invalid drug test results. Adding a cross-reference to paragraph (h)

of this section clarifies that the blanket permission to impose more stringent sanctions granted in this paragraph has one exception, as discussed with respect to paragraph (h) of this section. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.75(b) to the final rule 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. This 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, 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, this change meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

The final rule specifies three examples of actions that are 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 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 expects the licensee or other entity to permanently deny authorization to all of the individuals who were involved in the collusion.

The final rule does 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 § 26.185(g). Submitting a dilute specimen, in itself, does 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 former rule and in § 26.109(b)(1) of the final rule. Therefore, the final rule does 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 NRC used the phrase “for any test required under this part” in § 26.75(b) in the proposed rule to indicate that applicants for authorization who subvert or attempt to subvert a pre-access or random test are also subject to permanent denial of authorization. However, the NRC has changed this phrase in the final rule to “for any test required under 26.31(c).” This change clarifies the intent of the provision and is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. Although these individuals would not yet be performing any 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 duties. Therefore, it is necessary to ensure that any applicant who subverts or attempts to subvert the testing process is denied authorization.

Section 26.75(c) of the final rule amends former § 26.27(b)(3). Former § 26.27(b)(3) established 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 final rule retains the former sanction of a 5-year denial of authorization in these instances and adds two other instances in which a 5-year denial of authorization is required.

First, the final rule requires 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 change from the former rule 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 former sanction to alcohol consumption is also consistent with the revised FFD program performance objective in § 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, by reducing the risk to public health and safety and the common defense and security that the onsite use of alcohol poses, this change meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Second, the final rule adds the phrase "or while performing the duties that require the individual to be subject to this part" to address circumstances in which an individual may be performing the duties that require him or her to be subject to this part but is not doing so 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 former rule was 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 former rule did not specifically address such circumstances. The majority of licensees have appropriately interpreted the intent of the former rule, but the final rule adds this phrase to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

In addition, the final rule deletes the list of activities in the paragraph of the former rule that an individual is prohibited from performing. The final rule replaces this list with the summary term “authorization” for consistency with the use of this term throughout the final rule. As discussed with respect to § 26.4 [FFD program applicability to categories of individuals], the NRC presents the list of duties that require individuals to maintain authorization and to be subject to this part once in that section, rather than repeatedly throughout the rule, for consistency with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.75(d) of the final rule amends a portion of former § 26.27(c) that required licensees or other entities 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 former provision has raised implementation questions from licensees regarding the appropriate action to take in these circumstances. Licensees have questioned whether the former requirement was intended to deny authorization to an individual for some period of time, as required under former § 26.27(b)(2) through (b)(4), permanently deny authorization to the individual, or merely to record the resignation. Therefore, the final rule clarifies the intent of the former provision as follows:

The final rule establishes 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 paragraph establishes a 5-year denial of authorization because the confirmed positive drug or alcohol test result in combination with such a resignation, is 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 § 26.189 [Determination of fitness]. Therefore, prohibiting the individual from being granted authorization for a 5-year period gives the individual an opportunity to seek treatment and establish a 5-year history of sobriety, which is required to regain authorization under § 26.69 [Authorization with potentially disqualifying fitness-for-duty information]. This prohibition also ensures that such an individual is not granted authorization without having demonstrated that he or she has overcome the substance abuse problem. Therefore, the NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

In addition, for any type of FFD policy violation, this provision requires 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 is necessary to ensure that any licensees or other entities who may consider granting authorization to the individual in the future are aware of the individual's behavior and the nature of the FFD policy violation. Subsequent licensees and other entities will 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, § 26.75(g) prohibits a subsequent licensee or other entity from granting authorization to the individual under any circumstances. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness

and efficiency of FFD programs.

The NRC has moved the portion of former § 26.27(c) that referred to a refusal to provide a specimen for testing to § 26.75(b) of the final rule to meet Goal 6 of this rulemaking, regarding organizational clarity.

Section 26.75(e) of the final rule amends former § 26.27(b)(2) and expands its scope to include alcohol. The NRC no longer excludes the abuse of alcohol from the sanctions specified in this 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 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 the duties that require individuals to be subject to this part, this final rule imposes the same sanctions for abusing alcohol as those required for abusing drugs. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section 26.75(e)(1) retains but amends the intent of the second sentence of former § 26.27(b)(2). The former § 26.27(b)(2) stated 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 final rule requires licensees and other entities to immediately unfavorably terminate the individual's authorization for at least 14 days from the

date of the unfavorable termination, rather than “remove” the individual. With respect to the proposed rule, the final rule adds a clarification that the 14-day termination begins on the date of the unfavorable termination. The NRC has made this change because after publishing the proposed rule, it recognized the need for additional clarity in this provision to illustrate the NRC’s intent. At the public meetings discussed in Section I.D, 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. This change is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The stakeholders also requested that the agency eliminate from § 26.75(e)(1) the requirements in the former paragraph related to referring the individual to the EAP for assessment and counseling. 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 former provision as requiring them to provide EAP services to individuals whom they no longer employ. The NRC concurs that the intent of the former rule is for licensees and other entities to provide assessment and counseling services only in those instances when the licensee or other entity desires to reinstate the individual’s authorization. Therefore, the NRC has made this change, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule also moves the requirements in former § 26.27(b)(2) that were related to

permitting the individual to regain authorization to Subpart C [Granting and Maintaining Authorization] of the final rule instead of retaining them in § 26.75(e)(1) because § 26.75(e)(1) addresses sanctions for FFD policy violations, rather than FFD requirements for granting authorization. Subpart C addresses the 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 in § 26.69(b). The NRC has made this change to meet Goal 6 of this rulemaking to improve organizational clarity in the rule.

Section 26.75(e)(2) increases the length of the period for which licensees and other entities must deny an individual's authorization for a second confirmed positive drug or alcohol test result from 3 years in former § 26.27(b)(vii) to 5 years in the final rule. This change provides greater assurance that individuals who have had a second confirmed positive drug or alcohol 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 on 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 more stringent sanction for a second confirmed positive drug or alcohol test result provides greater deterrence to recidivism than the former 3-year period. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.75(f) of the final rule amends former § 26.27(b)(5). Former § 26.27(b)(5) stated that the sanctions for confirmed positive drug test results in former § 26.27 [Written policy and procedures] did not apply to the misuse of alcohol, valid prescriptions, and over-the-counter drugs, but required licensee FFD policies to establish sanctions that are sufficient to deter the misuse of those substances. The final rule requires 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. However, some licensees have imposed lesser sanctions for alcohol violations, an approach that is inconsistent with the NRC's intent. Therefore, the final rule rectifies this situation by explicitly requiring the same minimum sanctions for the abuse of alcohol as currently required for the use of illegal drugs. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 6 to improve clarity in the organization and language of the rule.

In addition, § 26.75(f) of the final rule requires licensees and other entities to impose the same sanctions as mandated for the abuse of illegal drugs if the MRO determines that the misuse of prescription drugs or over-the-counter medications resulting in a positive drug or alcohol test result represents substance abuse. The MRO makes this determination under § 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 over-the-counter cold and cough preparations containing alcohol or other active ingredients that may cause impairment. However, an individual who has a substance abuse problem may use the same substances. 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 this provision, 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 is required to impose the minimum sanctions specified in this 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 final rule requires the licensee or other entity to impose the sanctions for substance misuse that the licensee or other entity specifies in

the FFD policy.

The final rule also retains but revises the requirement in the last sentence of former § 26.27(b)(5). Section 26.75(f) retains the former requirement that sanctions for the misuse of prescription and over-the-counter drugs must be sufficient to "deter abuse of legally obtainable substances" because such misuse may lead to impairment on the job. However, the final rule eliminates the phrase "as a substitute for abuse of prescribed drugs" in the last sentence of former § 26.27(b)(5) because it unnecessarily limited the circumstances in which sanctions for the misuse of prescription and over-the-counter drugs must be imposed. The NRC has made these changes to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.75(g) of the final rule amends former § 26.27(b)(4). The NRC has moved the portions of the former paragraph that established requirements for granting authorization to an individual who has violated the licensee's or other entity's FFD policy to § 26.69 [Authorization with potentially disqualifying fitness-for-duty information] in Subpart C [Granting and Maintaining Authorization] of the final rule for organizational clarity because § 26.75(g) only addresses sanctions for FFD policy violations. This provision retains the portion of the former paragraph that required 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 final rule requires the permanent denial of an individual's authorization if he or she has another confirmed positive drug or alcohol test result after he or she has had authorization denied for 5 years under other paragraphs in this section. Requiring this more stringent sanction meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs because this provides reasonable assurance that individuals are trustworthy and reliable, as demonstrated by avoiding substance abuse, and increases the assurance that only individuals who are fit for duty are permitted to perform the duties listed in § 26.4 [FFD program

applicability to categories of individuals].

Section 26.75(h) and (i) of the final rule amends former § 26.24(d)(2). The former provision permitted 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, consistent with Goal 6 of this rulemaking, the final rule divides the former 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.

Section 26.75(h) prohibits licensees and other entities from taking administrative actions or imposing sanctions on an individual based on a positive test result from any initial drug test result reported by an HHS-certified laboratory. This section also permits 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 final rule requires that the urine specimen that yields a positive, adulterated, or substituted drug test result(s) must also appear to be a valid specimen, based on the results of validity screening or initial validity test results at the licensee testing facility. In addition, this section prohibits licensees and other entities from imposing sanctions or taking other actions in response to adulterated, substituted, or invalid validity screening or initial validity test results from a specimen in which no drug metabolites were detected. The NRC has added this prohibition 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 risks imposing substantial burdens on individuals from false positive, adulterated, substituted, or invalid test results. Therefore, the NRC has added this prohibition to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

With respect to the proposed rule, the final rule adds a provision that the licensee or other entity may not subject an individual to administrative action based upon validity testing results indicating that a specimen is of questionable validity. This change is based on analysis of public comment, which is discussed with respect to the term "questionable validity" in § 26.5 [Definitions].

Section 26.75(i)(1) through (i)(4) retains the requirements in former § 26.24(d)(2)(i) through (iv) that established 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 final rule adds a requirement for specimen validity testing (see the discussion of § 26.31(d)(3)(i) with respect to the addition of validity testing requirements in this rule and the requirement 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 final rule also revises the terminology used in the former provision to be consistent with the terminology used throughout the final rule (see the discussion of § 26.5 [Definitions] with respect to the new terminology adopted in the final rule) and updates the cross-references to other sections of the rule to be consistent with the organization of the final rule. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.77 Management actions regarding possible impairment.

The NRC has added § 26.77 [Management actions regarding possible impairment], which amends the requirements of former § 26.27(b)(1). The former section required licensees and other entities to remove impaired workers, or those whose fitness may be questionable, from performing activities within the scope of this part. The former provision also permitted licensees and other entities to return the individuals to duty only after the individuals were determined to be fit to safely and competently perform their duties. The final rule retains the intent of the former provision, but the terminology used in the section is consistent with the terminology used throughout the final rule. The NRC has updated cross-references to other sections of the rule, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. In addition, the agency has added several new requirements.

The NRC has added § 26.77(a) to the final rule to introduce and describe the purpose of the 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 their duties. The NRC has added this paragraph to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.77(b) of the final rule retains the portion of former § 26.27(b)(1) that required the licensee or other entity to take immediate action to prevent an individual from performing the duties that require him or her to be subject to this part if an individual appears to be impaired, or his or her fitness is questionable. This section of the final rule adds cross-references to §§ 26.27(c)(3), 26.207, and 26.209 (updated from the proposed rule) because those provisions provide exceptions to the requirement for immediate action. Section 26.27(c)(3) permits 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. Sections 26.207 and 26.209 contain the provisions for waivers and exceptions and self-declarations, which exempt individuals from the work hour controls of Subpart I [Managing Fatigue] under certain circumstances. The NRC has added the cross-references to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule also revises some terminology used in the former provision in response to stakeholder requests during the public meetings discussed in Section I.D. The stakeholders indicated that, because the former rule requires them to "remove" individuals whose fitness may be questionable, some FFD programs have interpreted the former paragraph as requiring them to terminate the individual's authorization. This was not the intent of the former provision. In this instance, the intent of the rule was for licensees and other entities to prevent the individual from performing the 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 final rule replaces the phrase, "removed from activities within the scope of this part," with the phrase, "prevent the individual from performing the duties," and makes other minor changes to the wording of the former requirement to clarify the intent of the provision. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.77(b)(1) retains the intent of former § 26.24(a)(3). This provision requires licensees and other entities to conduct drug and alcohol testing for cause. The final rule requires 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 is required. However, the final rule does not require the licensee or other entity to perform a drug test unless other physical or behavioral indicators of possible impairment are present.

The stakeholder comments received during the public meetings discussed in Section I.D 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 yields negative results, including those instances in which the alcohol test results are positive. The stakeholders suggested that the former 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 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 these 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 has eliminated it from the final rule. The final rule continues to require drug testing if there are behavioral or physical indications of impairment in addition to the smell of alcohol.

The NRC has added § 26.77(b)(2) to apply only to nuclear power plant licensees and C/Vs who are subject to Subpart I. With respect to the proposed rule, the final rule modifies the language of this provision to improve its clarity and to more clearly specify the NRC's intent. This section permits these entities to forego drug and alcohol testing and the determination of fitness process required by § 26.189 if a fatigue assessment conducted under § 26.211

confirms that the individual's observed behavior or physical condition is solely a result of fatigue. This section applies only to licensees and C/Vs who are subject to Subpart I because licensees not subject to Subpart I would not have the requisite training to evaluate whether the observed behavior is caused by fatigue. The NRC has made this change to meet Goal 2 of this rulemaking to ensure against worker fatigue at nuclear power plants and Goal 3 to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.77(b)(3) 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 Subpart I). Consistent with former § 26.27(b)(1), the final rule permits 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 § 26.189 for more details regarding the determination of fitness process). This section does 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 prohibits the licensee or other entity from assigning the impaired individual to perform the duties that require him or her to be subject to this subpart until a determination is made that the individual is fit to return to duty. The NRC has made this change to meet Goal 2 of this rulemaking to ensure against worker fatigue at nuclear power plants and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.77(c) of the final rule updates former § 26.27(d) to be consistent with current NRC notification procedures.

Subpart E—Collecting Specimens for Testing

Throughout Subpart E, the final rule makes minor clarifications to the proposed rule because of public comment, to accommodate conforming changes, and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. The final rule also makes more substantive changes to the proposed rule in this subpart because of public comment or to improve clarity in the organization and language of the rule. The substantive changes in this subpart can be found in §§ 26.81; 26.85(c)(1), (c)(2), and (e); 26.87(e); 26.89(a)(2) and (c); 26.91(e)(4); 26.109(b)(1); and 26.111(a), (c) and (d). These changes are discussed in detail below. However, other than the changes mentioned above, the final rule adopts the provisions of this subpart as proposed without change.

Section 26.81 Purpose and applicability.

This added section describes the purpose of Subpart E, which is to establish requirements for collecting specimens for drug and alcohol testing. The new section assists in locating provisions within the rule and is consistent with Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

The NRC revised the title of this section from “Purpose” in the proposed rule to “Purpose and applicability” in the final rule to reflect other modifications to this paragraph that the agency has made in response to public comments that the applicability of the proposed rule’s requirements was unclear. This paragraph specifies that the requirements of Subpart E apply to the licensees and other entities in § 26.3(a) through (d) to the extent that a C/V conducts drug and alcohol testing on which a licensee or other entity in § 26.3(a) through (c) relies. The provision further specifies the applicability of Subpart E’s requirements by also listing the categories of individuals who are subject to the subpart. These include the categories of individuals listed in § 26.4(a) through (e). In addition, licensees and other entities may choose

to conduct specimen collections and alcohol testing under the requirements of this subpart for the categories of individuals specified in § 26.4(f) and (g). However, §§ 26.4(j), 26.31(b)(2), and Subpart K permit licensees and other entities to rely on specimen collections and alcohol testing that are conducted under the requirements of 49 CFR Part 40, "Procedures for Transportation Workplace Drug Testing Programs" (65 FR 41944; August 9, 2001), for the reasons discussed with respect to those sections. In these instances, § 26.81 permits the specimen collections and alcohol testing to be performed under DOT's procedures, rather than those contained in Subpart E, for individuals who are subject to another Federal or State FFD program in § 26.4(j), FFD program personnel in § 26.31(b)(2), and the categories of individuals at a construction site in § 26.4(f). These changes meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

Section 26.83 Specimens to be collected.

The NRC has added § 26.83 [Specimens to be collected], which specifies the types of specimens that licensees and other entities must collect for initial and confirmatory drug and alcohol testing.

Section 26.83(a) requires licensees and other entities to collect either breath or oral fluids (i.e., saliva) for initial alcohol tests. The final rule continues to require collecting only breath specimens for confirmatory alcohol testing. The final rule permits the use of 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. Circumstances may arise, such as collecting a specimen of oral fluids from a donor who has impaired lung functioning, in which the use of these devices is more efficient than collecting breath specimens for both donors and the FFD program. Therefore, the permission to collect oral fluids for initial alcohol testing meets Goal 3 of this rulemaking 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 final rule is consistent with Goal 1 of the rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The final rule eliminates the use of blood as a specimen for alcohol testing at the donor's discretion, which was permitted in former § 26.24(g) and Section 2.2(d)(4) in Appendix A to Part 26. The final rule eliminates the former provisions related to blood alcohol testing for several reasons. Since the former 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 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 explains 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 the NRC envisioned when promulgating the provisions for voluntary testing of blood specimens has not been realized in practice. The former requirement

has also been costly for licensees. Licensees must ensure that an individual who is trained to draw blood is available to do so should a donor request blood testing. Based on information provided by stakeholders at the public meetings discussed in the preamble to the proposed rule, 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, the agency has deleted from the final rule references to collecting and testing blood specimens for alcohol.

Section 26.83(b) retains, but makes explicit, the implied requirement in the first sentence of former § 26.24(b) (and other provisions that are interspersed throughout the former rule) for licensees and other entities to collect only urine specimens for drug testing. When the former 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 HHS has published proposed revisions to its guidelines (69 FR 19673; April 13, 2004) that would permit the use of 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 HHS has published final revisions to its guidelines related to these types of specimens. The revised HHS Guidelines will establish 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 final 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 § 26.31(d)(5) [Medical conditions]. The reasons are as discussed with respect to that section.

Section 26.85 Collector qualifications and responsibilities.

This added section replaces the collector qualifications and training requirements specified in the definition of “collection site person” in the former rule and in former Sections 1.2, 2.2(d), and 2.4(b) in Appendix A to Part 26. This section retains the intent of the former provisions, but the final rule groups the requirements together to improve organizational clarity. In addition, the final rule amends the former collector qualifications and training requirements to increase the consistency of Part 26 with the requirements of other Federal agencies and incorporates the lessons learned from those programs as discussed with respect to Goal 1 of this rulemaking.

Section 26.85(a) [Urine collector qualifications] provides more detailed requirements for urine collector qualifications and training than are contained in the former definition of “collection site person” and former Section 2.2(d) in Appendix A to Part 26. The final rule requires urine collectors to be knowledgeable of the requirements of this part, the FFD policy and procedures of the licensees or other entities for whom they perform collections, and to keep current on any changes to urine collection procedures. These changes increase the consistency of urine collector qualification requirements with those of other Federal workplace drug testing programs as well as consistency in urine collection procedures among FFD programs that are subject to this subpart.

Section 26.85(a) retains the requirements in former Section 2.2(d) that urine collectors must receive training to perform their duties and demonstrate proficiency in applying the requirements of this section before serving as a collector. Section 26.85(a)(1) through (a)(4) lists the topics that the final rule requires collector training to address. Section 26.85(a)(1) requires 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. Section 26.85(a)(2) requires

training in methods to address “problem” collections. These may include, but are not 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. Section 26.85(a)(3) requires the training to instruct collectors on correcting collection problems. These may include, but are not limited to, a donor refusing to cooperate with the collection process or an incident in which a urine specimen is spilled. Section 26.85(a)(4) requires training so that a collector is knowledgeable in maintaining the integrity of the specimen collection and transfer process, and ensuring that donors’ privacy and modesty are maintained. The NRC added these requirements to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.85(a)(4) retains the portion of former Section 2.2(d)(1) in Appendix A to Part 26 that required collector training to emphasize 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.

The NRC added § 26.85(b) [Alcohol collector qualifications] to specify requirements related to alcohol collector qualifications and training. Portions of this section are the same as the requirements for urine collectors in § 26.85(a), including the first three sentences of § 26.85(b), and (b)(4) and (b)(5). The agency added these requirements here for the same reasons discussed with respect to the first three sentences of § 26.85(a), and (a)(3) and (a)(4), respectively. The final rule repeats 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 makes it easier to locate the requirements that apply to urine or alcohol collectors and meets Goal 6 of the

rulemaking to improve clarity in the organization of the rule.

Section 26.85(b)(1) and (b)(3) requires alcohol collectors to receive training that addresses the alcohol testing requirements of this part and methods to address “problem” collections. These include, but are not limited to, collections involving “shy lung” problems or attempts by a donor to tamper with a specimen. In contrast, to § 26.85(a)(2), which addresses “shy bladder” problems in urine collections, the final rule does not incorporate the related DOT procedures for evaluating “shy lung” problems in alcohol collections. During the public meetings discussed in the preamble to the proposed rule, 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 final rule is necessary. The stakeholders reported that donors have not experienced problems related to “shy lung,” based on their experience implementing the breath testing requirements of Part 26 since the rule was first promulgated. Therefore, § 26.85(b)(3) requires 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 does not establish requirements for responding to “shy lung” problems in the rule.

The final rule adds § 26.85(b)(2) to require alcohol collectors to be trained in the operation of the particular alcohol testing device(s) (i.e., the ASDs and EBTs) to be used in conducting alcohol tests, consistent with the most recent version of the manufacturers’ instructions. The final rule adds this requirement 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 final rule adds this requirement to ensure that alcohol test results continue to be accurate and cannot be challenged on this basis. The changes are also consistent with the alcohol collector

training requirements of other Federal agencies.

Section 26.85(c) [Alternative collectors] amends the last sentence of former Section 2.2(d)(2) in Appendix A to Part 26. The former provision permitted medical personnel to perform specimen collections without receiving the required training for non-medical collectors. The final rule permits medical personnel to conduct specimen collections for the purposes of this subpart only under the conditions specified in § 26.85(c)(1) through (c)(5). These conditions may include, but are not limited to, the collection of specimens for post-event testing by a nurse or medical technician at a hospital. The final rule limits 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 on these individuals to collect specimens for drug and alcohol testing, as discussed with respect to § 26.4(i)(1). Therefore, the final rule permits 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 otherwise requires medical personnel who do not meet the criteria specified in § 26.85(c)(1) through (c)(5) to receive the same training as non-medical collectors. The NRC made this change to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, by reducing the likelihood of errors and legal challenges to test results. In addition, the final rule also makes minor changes to the organization of this paragraph in response to a public comment indicating a lack of clarity in the same provision in the proposed rule.

The NRC has eliminated former Section 2.2(d)(4) in Appendix A to Part 26, which required that donors must be informed of the option to request blood testing. The agency

eliminated the former requirement because the final rule no longer permits donors to request blood testing for alcohol, as discussed with respect to § 26.83(a).

Section 26.85(d) amends former Section 2.7(o)(5) [Personnel available to testify at proceedings] in Appendix A to Part 26. This section required the licensee testing facility and HHS-certified laboratory to make available qualified individuals to testify in administrative or disciplinary proceedings related to drug and alcohol test results. The final rule adds an explicit requirement for collection site personnel to be available to testify at proceedings because the former provision implied, but did not explicitly state this requirement. When 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 that may not be co-located with the collection site. Therefore, the NRC has added this paragraph to retain the former rule'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 final rule moves the requirements in the former paragraph that addressed the availability of personnel to testify in proceedings related to drug test results from the licensee testing facility to § 26.139(c) of Subpart F [Licensee Testing Facilities] and those related to HHS-certified laboratories to § 26.153(f)(2) of Subpart G [Laboratories Certified by the Department of Health and Human Services].

The NRC added § 26.85(e) to the final rule in response to a public comment noting that the proposed rule did not include a requirement for licensees and other entities to ensure that personnel files are maintained for collectors. The new paragraph establishes requirements for personnel files for collectors to document their training and other qualifications for the positions they hold. This documentation may be necessary in administrative and/or legal proceedings

related to an alcohol or drug test result.

26.87 Collection sites.

The NRC has reorganized requirements related to specimen collection sites in the former rule and grouped them together in this section. Requirements related to collection sites were distributed among several different sections in Appendix A to Part 26 of the former rule. The agency made this change to improve organizational clarity in the rule.

Section 26.87(a) amends former Section 2.4(a) in Appendix A to Part 26. This former section required FFD programs to designate collection sites and ensure that they are fully equipped to collect specimens for testing. The final rule deletes references to blood specimens because the final rule no longer provides donors with the option to request blood testing for alcohol for the reasons discussed with respect to § 26.83(a). The final rule adds a requirement for collection sites to be capable of alcohol testing that the former section implied but did not explicitly state. The agency made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule. This section retains the permission in the former rule for licensees and other entities to use properly equipped mobile collection facilities.

Section 26.87(b) revises the first sentence of former 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 retains the former 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 increases the consistency of Part 26 with the alcohol testing procedures of other Federal agencies and assures greater privacy for donors who are subject to FFD programs that did not provide visual privacy under the former rule. The NRC made this change to meet Goal 7 of this rulemaking to protect the privacy of individuals who are subject to Part 26. For organizational

clarity, the final rule moves the former requirements in Section 2.4(f) in Appendix A to Part 26 that are related to collecting a specimen under direction observation to § 26.115 [Collecting a urine specimen under direct observation].

Section 26.87(c) retains only the portion of former Section 2.7(m) in Appendix A to Part 26 that required licensees' and other entities' contracts for collection site services to permit unfettered NRC, licensee, and other entity access to collection sites for unannounced inspections. The final rule moves the portions of the former section that apply to HHS-certified laboratories to § 26.153(f) of Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity. In addition, § 26.87(c) adds 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. The final rule adds this requirement for access to documentation for consistency with the HHS Guidelines, which also require collection sites to provide information and documentation as part of inspections and audits. Therefore, this change meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. The agency also added the term "audit" to this section because, although the NRC conducts inspections, licensees and other entities are required to conduct audits under § 26.41 [Audits and corrective action]. Adding this term to this paragraph increases the clarity of its language, consistent with Goal 6 of the rulemaking.

Section 26.87(d) revises former Section 2.4(c) in Appendix A to Part 26 to clarify requirements for assuring collection site security and the integrity of specimen collection procedures. For organizational clarity, the final rule groups requirements related to assuring the security of a licensee's or other entity's designated collection site in this paragraph. For the same reason, the final rule moves to § 26.87(f) the requirements contained in former

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. Section 26.87(d) includes other clarifying changes to former Section 2.4(c) in Appendix A to Part 26, in response to stakeholder requests at the public meetings discussed in Section IV.D.

Section 26.87(d)(1) retains the first sentence of former Section 2.4(e) in Appendix A to Part 26 and permits only authorized personnel to have access to any part of a collection site in which specimens are collected and stored. For organizational clarity, the final rule moves this requirement to this section because it addresses the topic of collection site security.

Section 26.87(d)(2) amends the second sentence of former Section 2.4(c) in Appendix A to Part 26. The former provision required collection sites to be secure, and the final rule adds examples of acceptable methods to assure collection site security. The NRC added these examples in response to stakeholder requests during the public meetings discussed in the preamble to the proposed rule. The stakeholders noted that the requirement that collection sites "must be secure" has raised many implementation questions. Therefore, the final rule adds 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 agency made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.87(d)(3) amends the third sentence in former Section 2.4(c) in Appendix A to Part 26. The former provision required that the portion of any facility that is not dedicated solely to drug and alcohol testing must be secured during testing. The final rule retains that requirement and combines it with the third sentence of former Section 2.4(c)(1) in Appendix A to Part 26. The provision requires the protection of the facility against unauthorized access during the collection. The final rule replaces the phrase, "in the case of a public restroom," in

the last sentence of former 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 NRC makes these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The agency has added § 26.87(e) to specify the steps that licensees and other entities must take to deter dilution and adulteration of specimens during urine collections. This section retains and amends portions of former Section 2.4(g) in Appendix A to Part 26.

Section 26.87(e)(1) relaxes the former requirement in Section 2.4(g)(1) of Appendix A to Part 26 to use a bluing agent in any source of standing water, such as a toilet bowl or tank. The final rule permits licensees and other entities to use colors other than blue. However, the final rule prohibits use of a yellow coloring agent because it precludes 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 relaxation does not affect the accuracy of drug tests but gives FFD programs increased flexibility in the choice of coloring agents. The agency made this change in response to stakeholder requests during the public meetings discussed in the preamble to the proposed rule and to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.87(e)(2) retains the second sentence of former Section 2.4(g)(1) in Appendix A to Part 26, which requires sources of standing water to be secured, but shortens it without changing the intended meaning of the requirement. The agency made this change to improve clarity in the language of the rule.

The final rule adds § 26.87(e)(3) 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 paragraph also requires the collector to inspect the enclosure to ensure that no potential adulterants are available before the donor enters the stall or enclosure. The agency intends

these requirements to prevent possible donor attempts to subvert the testing process by adulterating a urine specimen with materials that are available at the collection site. This provision meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs. The provision is also consistent with the related requirements of other Federal agencies.

Section 26.87(f) reorganizes former 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 final rule groups these requirements together in a single paragraph and separates them from those related to collecting specimens at a designated collection site in § 26.87(d) and (e) to make it easier to locate these requirements within the rule. The NRC made this change to improve organizational clarity in the rule.

Section 26.87(f)(1) amends former Section 2.4(c)(1) in Appendix A to Part 26, which established requirements for securing a location that is not a designated collection site but will be used for a specimen collection(s). The final rule requires 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 former rule required only the posting of a sign. However, stationing an individual to guard access is at least as effective. The final rule permits an individual to guard access to the collection area in response to stakeholder requests for this flexibility during the public meetings discussed in the preamble to the proposed rule. This change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.87(f)(2) retains the third sentence of former Section 2.4(g)(10) in Appendix A to Part 26 that requires using a water-coloring agent, 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.

Section 26.87(f)(3) retains the requirement in the second sentence of former Section 2.4(g)(10) that the collector must be the same gender as the donor in the exceptional event of a specimen collection occurring at a location other than the FFD program's designated collection site. However, if a collector of the same gender is unavailable, the rule permits another person of the same gender who is instructed in the requirements of Subpart E [Collecting Specimens for Testing] to assist in the collection. The provision requires 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 rule requires documentation of the observer's identity 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 § 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, is consistent with the procedures of other Federal agencies and reduces potential embarrassment to the donor. Therefore, this change meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, and Goal 7 to protect the privacy of individuals who are subject to Part 26.

Section 26.87(f)(4) requires 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. This paragraph amends the fifth and sixth sentences of former Section 2.4(g)(10) in Appendix A to Part 26 that described the required sequence of actions during a specimen collection and specified that a donor is permitted to flush the toilet after a specimen donation. The final rule eliminates the option for the donor to flush the toilet and directs the collector to instruct the donor not to flush the toilet. The change reduces the

possibility that a donor could dispose of evidence of a subversion attempt by flushing it down the toilet. Section 26.87(f)(4) directs the collector to inspect the toilet bowl and area once he or she receives the specimen from the donor. The final rule adds these provisions to reduce the opportunities for a donor to subvert the testing process at a location that is not a designated collection site to meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs. The requirements also meet Goal 1 to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.87(f)(5) amends the portions of former Section 2.4(c)(2) in Appendix A to Part 26 that defined requirements for maintaining control of specimens that are not collected at a designated collection site. The final rule permits an "authorized individual," including, for example, a security officer or hospital medical technician, to maintain physical custody and control of specimens, rather than only the collector, as the former rule required. The licensee or other entity must designate the "authorized individual" and ensure that he or she is instructed in his or her responsibilities for maintaining custody and control of the specimen. The authorized individual's custody of the specimen must 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 § 26.39 or legal proceedings. This change continues to ensure specimen integrity and security, but responds to industry experience, as described by stakeholders at the public meetings discussed in the preamble to the proposed rule. 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 NRC made this change to meet Goal 5 of this rulemaking, to improve Part 26 by eliminating or modifying unnecessary requirements, while also continuing to meet Goal 7 to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.89 Preparing to collect specimens for testing.

This added section describes the preliminary steps that the collector and donor must take before specimens will be collected for drug and alcohol testing. This section reorganizes and amends portions of the former Appendix A to Part 26, and adds several new requirements. The final rule presents these requirements in a new section to facilitate locating them within the final rule to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.89(a) provides more detailed requirements than those contained in former 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 former rule required 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 the preamble to the proposed rule, some stakeholders indicated that the lack of specificity in the former 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 was not the NRC's intent. Therefore, under this new provision, when informed that an individual who was selected for testing has not appeared at the required time, FFD program management must 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 final rule requires the licensee or other entity to impose the sanctions specified in § 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 the investigation does not identify evidence of a subversion attempt, the final rule prohibits the licensee or other entity from imposing sanctions and requires testing the individual at the earliest reasonable and

practical opportunity after the individual is located. The NRC has added these more detailed requirements to strengthen the rule's effectiveness in preventing subversion by ensuring that a failure to appear for testing is investigated to increase the likelihood of detecting a willful attempt to avoid testing. In addition, the requirements prevent an individual from being subject to a permanent denial of authorization, as required under § 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. The agency has made these changes to meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs, and Goal 7 to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.89(b) reorganizes and expands former Section 2.4(g)(2) in Appendix A to Part 26, which required the collector to ensure that an individual who arrives at the collection site for testing is positively identified. The final rule adds more detailed requirements for the reasons discussed with respect to each requirement.

Section 26.89(b)(1) retains the requirement in former Section 2.4(g)(2) in Appendix A to Part 26 for the collector to positively identify the donor before beginning a collection. This section specifies the types of photo identification that the licensee or other entity may accept to establish a donor's identity.

Section 26.89(b)(2) amends the portion of former Section 2.4(g)(2) in Appendix A to Part 26 that directed the collector to stop the collection if the individual cannot be positively identified. The amended provision directs the collector to proceed with the collection and inform FFD program management that the donor did not present acceptable photo identification. This paragraph requires FFD management to take the necessary steps to determine whether the lack of identification is an attempt to subvert the testing process. However, the provision retains the former requirement for the collector to delay the collection until the individual can be identified if it is a pre-access test. The NRC has made these changes for several reasons.

First, lessons learned from implementing the former rule have indicated that the large majority of failures to present acceptable identification result from 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 ensures that test results are available and accurate from donors who are currently authorized and whose identity the licensee or other entity has previously confirmed. Therefore, this change meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Second, the former 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 provides 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 new requirement strengthens the effectiveness of FFD programs in detecting attempts to subvert the testing process.

The final rule modifies the proposed rule to permit an individual's supervisor, except for pre-access tests, to positively identify an individual who appears for testing without acceptable

photo identification. The NRC made this change in response to a public comment, which noted that under many FFD programs, supervisors are trusted to notify donors that they have been selected for random testing, and, therefore, it is reasonable to trust supervisors also to verify a donor's identity. The change increases 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 (Goal 4 of this rulemaking).

Section 26.89(b)(3) retains the former requirement to delay the specimen collection until the individual presents acceptable identification if it is a pre-access test, at the request of stakeholders during the public meetings discussed in the preamble to the proposed rule. The stakeholders noted that the former 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 does not yet have access to sensitive information, radiological materials, or safety systems and equipment. Furthermore, stakeholders noted that retaining the former provision saves licensees and other entities from the expense associated with collecting and testing a specimen from the wrong individual. Therefore, the NRC believes it is reasonable to retain the former requirement as it relates to pre-access tests.

Section 26.89(b)(4) updates former Section 2.4(g)(4) and 2.4(g)(23)(ii) in Appendix A to Part 26, in which, before any specimens are collected, donors were required to list the prescription and over-the-counter medications they had 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 final rule eliminates the requirement to list medications prior to specimen collection and testing. The final rule requires donors to provide medication information to the MRO only in the event of positive, adulterated, substituted, or invalid confirmatory validity and/or drug test result to enhance their rights to privacy under the rule.

This revised requirement is also consistent with the procedures of other Federal agencies and meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.89(b)(4) also adds a requirement for the collector to explain the testing procedure to the donor. Former Section 2.2(d)(3) in Appendix A to Part 26 required providing individuals who are subject to testing with standard written instructions setting forth their responsibilities. However, the NRC is aware that individuals typically receive these instructions as part of the training that is required under former § 26.21 [Policy communications and awareness training] rather than at the collection site before starting the specimen collection process. This was not the intent of Section 2.2(d)(3) in Appendix A to Part 26. Rather than retaining and clarifying the former provision for standard written instructions that some individuals have may difficulty comprehending, the final rule adopts the related practices of other Federal agencies, which require the collector to explain the testing procedure to the donor. This change ensures that individuals are informed of the testing process in which they must participate and their responsibilities. It also meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 1, by enhancing the consistency of Part 26 with the requirements of other Federal agencies.

The NRC added § 26.89(c) to ensure that the donor is aware of his or her responsibilities to cooperate with the specimen collection process. This paragraph responds to reports from stakeholders at the public meetings discussed in the preamble to the proposed rule that some donors have attempted to obstruct or delay the collection process on the basis that the former rule implied, but did not explicitly state, the donor's responsibility to cooperate with the collection process. Therefore, the new provision eliminates that basis for obstructing or delaying collections, which improves the effectiveness and efficiency of FFD programs,

consistent with Goal 3 of this rulemaking.

This section also requires the collector to inform the donor that a failure to cooperate in the specimen collection process is considered a refusal to test and may result in a permanent denial of authorization under § 26.75(b). In response to public comment, the final rule adds examples to those in the proposed rule describing behavior that may be determined to be a refusal to test. In addition to leaving the collection site before the collection is complete, the final rule adds behaving in a confrontational manner that disrupts the testing process; admitting to the collector that the donor has substituted, diluted, or adulterated the specimen; or the collector finds that the donor has a device, such as a prosthetic appliance, the purpose of which is to interfere with providing an actual urine specimen. Other examples could include a donor refusing to permit the collector to examine the contents of the donor's pockets or the donor refusing to wash his or hands when directed by the collector. The final rule does not provide an exhaustive list of behaviors that comprise a refusal to test because they are too numerous to list. However, the NRC has added these examples for increased clarity in the rule. Informing donors of the potential consequences of failing to cooperate in the collection process, in advance, is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26. The requirements of this section also meet Goal 1 to improve the consistency of NRC requirements with those of other Federal agencies.

Section 26.89(d) retains the last two sentences of former Section 2.4(e) in Appendix A to Part 26. These provisions 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 NRC has retained these provisions in this paragraph because they relate to the topic of this section, which is preparing for specimen collections, to ensure that collectors are aware of this requirement before they begin collecting any specimens. The

change improves the organizational clarity of the rule.

Section 26.91 Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use.

This added section amends requirements in the former rule that addressed alcohol testing devices and methods of use. The requirements in the former rule that are related to this topic appeared in former § 26.24(g) and Sections 2.4(g)(18) and 2.7(o)(3)(ii) in Appendix A to Part 26. This section combines these requirements, amends the former requirements, and adds others. The final rule groups these requirements in one section to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

The agency added § 26.91(a) [Acceptable alcohol screening devices] to permit the use of alcohol screening devices (ASDs) for initial testing and establish requirements for the ASDs that may be used. Acceptable ASDs 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 (66 FR 22639; May 4, 2001, and subsequent amendments). Former Section 2.7(o)(3)(ii) in Appendix A to Part 26 limited 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 is consistent with other Federal agencies' procedures for workplace alcohol testing. Therefore, the change meets Goal 1 of this rulemaking 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 provides 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 final rule's permission to use ASDs that are listed on NHTSA's CPL for ASDs for initial alcohol testing meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements by increasing FFD programs' flexibility in administering initial alcohol tests.

Section 26.91(b) [Acceptable evidential breath testing devices] amends former Section 2.7(o)(3)(ii) in Appendix A to Part 26 and establishes new requirements for the EBTs that licensees and other entities must use for confirmatory alcohol breath testing. The new section requires licensees and other entities to use EBTs that are listed on the most recent version of NHTSA's CPL for evidential breath testing devices without an asterisk (67 FR 62091; October 3, 2002, and subsequent amendments) when conducting confirmatory alcohol tests, and permits licensees and other entities to use these EBTs for conducting initial alcohol tests. The EBTs that are listed without an asterisk 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 confirmatory testing at the revised alcohol cutoff levels specified in § 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 new requirement to use these EBTs permits two additional changes to the alcohol testing procedures contained in former 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 §§ 26.95(c) and 26.101(c), rather than the two specimens that were required for each test under the former rule; and (2) conducting both the initial and confirmatory tests (if a confirmatory test is required) using the same EBT in § 26.101(d). As discussed further with respect to §§ 26.95(c) and 26.101(c) and (d), these changes to the former alcohol testing requirements 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. Therefore, this change meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines; Goal 3 to improve the efficiency of FFD programs; and Goal 5 to improve Part 26 by eliminating or modifying unnecessary requirements.

The NRC added § 26.91(c) [EBT capabilities] 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 § 26.91(c)(1) through (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 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 § 26.91(c)(4) through (c)(6) ensure that test results will be accurate by requiring collectors to verify before each test that the instrument is functioning properly and there will be no carryover effects from previous testing. These capabilities improve the effectiveness and efficiency of confirmatory alcohol testing by limiting the need to cancel test results due to instrument errors, as required under § 26.91(e)(3). Using EBTs that have the required capabilities for confirmatory alcohol tests protects donors' rights to accurate test results, provides greater assurance that test results will withstand any legal challenges, and improves FFD programs' abilities to identify tests that instrument errors may have affected. Therefore, these requirements meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC added § 26.91(d) [Quality assurance and quality control of ASDs] to establish

quality assurance and quality control requirements for ASDs. These 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, the test would not detect a donor who has an alcohol concentration that exceeds the cutoff levels established in this part, and the donor may be permitted to perform duties while impaired, potentially creating an unacceptable risk to public health and safety or the common defense and security. The final rule continues to require confirmatory testing if initial alcohol test results are positive, so false positive test results from an ASD lead to confirmatory testing, which provides accurate test results. False positive test results from initial testing 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 paragraph are necessary to maintain the effectiveness of FFD programs, which is Goal 3 of this rulemaking.

The agency added § 26.91(d)(1) 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. 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. This paragraph requires 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 § 26.91(d), the new provision is necessary to maintain the effectiveness of FFD programs that rely on ASDs for initial alcohol testing.

The NRC added § 26.91(d)(2) to prohibit licensees and other entities from using an ASD that fails the quality control checks that are specified in the most recent version of the manufacturer's quality assurance plan or that has passed its expiration date. This prohibition is 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.

The NRC added § 26.91(d)(3) to require licensees and other entities to follow the device use and care requirements that are specified in § 26.91(e) for any ASD that tests breath specimens. The agency added this requirement 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 (67 FR 62091: October 3, 2002, and subsequent amendments). Those ASDs that do test breath specimens and are used for confirmatory testing have more detailed quality assurance and quality control provisions because their results must be legally defensible.

Section 26.91(e) [Quality assurance and quality control of EBTs] establishes new quality assurance and quality control requirements for EBTs. The new requirements are consistent with those of other Federal agencies that require workplace alcohol testing and, therefore, update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.91(e)(1) adds 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 final rule requires 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 provision is intended to ensure that the EBT will not provide false test results from improper storage or use.

Section 26.91(e)(2) adds 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 requirement is necessary to ensure that the calibrating units used by licensees and other entities meet minimum standards and provide accurate results.

The final rule adds § 26.91(e)(3) to address circumstances in which an EBT fails an external calibration check. This section requires the licensee or other entity to take the EBT out of service and prohibits its use until it has been repaired and passes an external calibration check. 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.

The NRC moved and amended the requirement in proposed § 26.91(e)(3) to cancel any positive confirmatory alcohol test results that were obtained from an EBT that fails an external calibration check and also to cancel the results of any tests that were conducted with that EBT subsequent to its last successful external calibration check. The final rule retains this requirement in § 26.91(e)(4)(i), but presents it as one of two options licensees and other entities

must implement if an EBT fails an external calibration check. The final rule adds a second option for handling circumstances in which an EBT fails an external calibration check in § 26.91(e)(4)(ii). This new section permits licensees and other entities to conduct an external calibration check of the EBT after each positive confirmatory alcohol test result. If the EBT fails the check, the provision requires the collector to cancel the donor's test result and perform another initial and confirmatory alcohol test, if necessary, using a different EBT. The requirements to cancel tests from an EBT that has failed an external calibration check are necessary to protect donors' right to accurate testing 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.

The NRC added § 26.91(e)(4)(ii) in response to a public comment on proposed § 26.91(e)(3). The commenter stated that canceling donors' positive confirmatory test results from an EBT that fails an external calibration check may not adequately protect donors' rights under the rule, if a licensee or other entity performs external calibration checks at the manufacturers' recommended intervals. The commenter noted that most EBT manufacturers' recommended intervals for conducting external calibration checks are 1 month, which could result in several canceled tests, if an EBT has yielded false positive test results that are only discovered when the EBT fails the monthly check. However, if the licensee or other entity has already imposed sanctions on a donor for a positive confirmatory alcohol test result from the EBT, the donor will experience the adverse consequences of those sanctions, which may include job loss, before the licensee or other entity identifies the instrument malfunction and cancels the donor's confirmed positive test result.

The NRC considered several options to address this concern, including requiring more frequent external calibration checks, but could not identify a technical basis for establishing schedules that would be more appropriate for every EBT on the NHTSA list than those

recommended by the EBT manufacturers. Further, the agency recognizes that canceling tests imposes a burden on licensees and other entities as well as on donors and expects that licensees and other entities will likely choose to conduct external calibration checks more often than recommended by the EBT manufacturers to avoid canceling multiple tests. Therefore, the final rule retains the proposed requirement as an option in § 26.91(e)(4)(i), but adds a second option for handling circumstances in which an EBT fails an external calibration check in § 26.91(e)(4)(ii). Under the latter provision, it is unnecessary for a licensee or other entity to cancel any previous donors' confirmed positive alcohol test results from using the EBT because the licensee or other entity will perform the external calibration check after every positive confirmatory test result and no other donors will have been affected by false positive test results from an EBT that fails the check. Under this option, a donor will not be subject to adverse consequences for a false positive test result because the malfunction will be detected before the licensee or other entity imposes any sanctions. The NRC has added this provision to meet Goal 7 of the rulemaking to protect donors' privacy and other rights (including due process) under the rule.

The final rule renumbers as § 26.91(e)(5) the provision contained in § 26.91(e)(4) of the proposed rule. This section requires an EBT manufacturer or a maintenance representative or other individual who is certified by the manufacturer, a State health agency, or other appropriate State agency to inspect, maintain, and calibrate the EBT. This new provision ensures that qualified personnel perform inspection, maintenance, and calibration of EBTs (1) to ensure that the EBTs used in Part 26 programs continue to provide accurate test results, and (2) because the experience of other Federal agencies that 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. The final rule adds "or other individual who is certified" to the proposed provision because some licensees and other entities

may choose to obtain the required certification for their FFD program personnel or other employees, and the NRC does not intend to prohibit this practice.

Section 26.93 Preparing for alcohol testing.

This added section expands on former Section 2.4(g)(18) in Appendix A to Part 26, which specified procedures for alcohol testing. The final rule provides more detailed procedures than the former 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. The agency added more detailed requirements for the reasons discussed in Section IV.B.

Section 26.93(a) contains more detailed procedures for implementing the requirement in the first sentence of former Section 2.4(g)(18) in Appendix A. That provision instructed 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). Section 26.93(a)(1) through (a)(6) requires the collector to provide the donor with more detailed information about mouth alcohol and the testing process than was required under the former rule and document that the information is provided. Providing more detailed requirements for the 15-minute waiting period improves 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. Section 26.93(a)(1) retains the former 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 adds a requirement for the collector to advise the donor to avoid these activities during the collection process. Section 26.93(a)(2) permits alcohol testing to proceed if the donor states that none of the activities listed in § 26.93(a)(1) has occurred, while § 26.93(a)(3) retains the former

requirement for a 15-minute waiting period before a donor may be tested if he or she had engaged in the activities listed in § 26.93(a)(1). Section 26.93(a)(4) adds 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. Section 26.93(a)(5) adds 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). Section 26.93(a)(6) adds a requirement for the collector to document that he or she has communicated the instructions to the donor. The additional requirements for the collector to communicate with the donor about the potential effects on test results of the activities listed in § 26.93(a)(1) ensure that donors clearly understand the reasons for avoiding those activities and the potential consequences of engaging in them to protect their rights to accurate test results under the rule. The requirement for the collector to document that the instructions were communicated to the donor ensures that the collector does not inadvertently omit the instructions and, therefore, improves the legal defensibility of the collection procedure, should a donor challenge it.

The final rule adds § 26.93(b) 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 requirements decrease the likelihood that a donor's test results will fall below the program's cutoff levels as a result of metabolic processes over time, which could prevent the detection of proscribed alcohol consumption and drug use. Delays between the time at which a donor reports for testing and the time at which testing occurs continue to be permitted for tests conducted under conditions other than for cause, because, in contrast to for-cause testing, there is no reason to believe that an individual may have used drugs or alcohol in violation of the FFD policy. Therefore, there is no basis for a concern that metabolic processes may cause inaccurate test results. The new provision is consistent with the related regulations

of other Federal agencies.

Section 26.95 Conducting an initial test for alcohol using a breath specimen.

Section 26.95 replaces portions of former Section 2.4(g)(18) in Appendix A to Part 26 that specified procedures for conducting an initial test for alcohol. Collectors follow the procedures in this section when using ASDs that test breath specimens and EBTs. The new section increases the consistency of Part 26 with the procedures of other Federal agencies for workplace alcohol testing. Consistent with other agencies' procedures, the final rule eliminates the requirement in former 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 former 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 new section are followed. Therefore, the final rule amends the former 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.

The agency added § 26.95(a) 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 final rule adds the phrase, "as soon as reasonably practical," to this paragraph in response to stakeholder comments at the public meetings discussed in the preamble to the proposed rule. 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 § 26.93 [Preparing for alcohol testing] to ensure the accuracy of the test result. 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 § 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 final rule adds the phrase, "as soon as reasonably practical," to permit reasonable delays in testing associated with outage planning.

Section 26.95(b)(1) permits the donor to select a mouthpiece to be used for his or her test, at the collector's discretion. The rule does not require the collector to permit the donor to select the mouthpiece. However, this practice 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 may attempt to subvert the testing process by 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.

In § 26.95(b)(2), the NRC has added a requirement for the collector to open the mouthpiece packaging and insert it into the device in view of the donor for the same reason described with respect to § 26.95(b)(1).

Section 26.95(b)(3) requires the donor to blow into the mouthpiece for at least 6 seconds in order to obtain an adequate breath sample. The NRC deleted the requirement to obtain the specimen from the end of the breath exhalation in former Section 2.4(g)(18) in Appendix A to Part 26 because it is unnecessary, based on improvements to breath-testing

technology.

Section 26.95(b)(4) requires the collector to show the test result to the donor. This 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 requirement is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) 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.

Section 26.95(b)(5) requires the collector to ensure that the test result record can be associated with the donor and is maintained securely, consistent with the many provisions throughout the former and final rules that the chain of custody must be maintained for specimens and the associated documentation of test results. Sections 26.129 [Assuring specimen security, chain of custody, and preservation] and 26.159 [Assuring specimen security, chain of custody, and preservation] establish similar requirements for urine specimens at licensee testing facilities and HHS-certified laboratories, respectively.

The NRC has added § 26.95(c) to require the collection of only one breath specimen for the initial test unless problems in the collection require repetition of the collection. Problems in the collection may include, but are not 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 must rely on the result from the first successful collection in determining the need for confirmatory alcohol testing. If the procedures specified in this paragraph are followed, relying on one breath specimen for the initial test, rather than the two required in the former rule, increases the consistency of Part 26 collection procedures with those of other Federal agencies, in accordance with Goal 1 of this rulemaking. The new requirement also reduces the

time required for breath specimen collections without compromising the accuracy, validity, or reliability of the test results. Therefore, the provision also meets Goal 3 to improve the efficiency of FFD programs.

Section 26.97 Conducting an initial test for alcohol using a specimen of oral fluids.

The NRC added this section to establish requirements for conducting initial alcohol tests using an ASD for testing oral fluids specimens. The final rule permits licensees and other entities to rely on ASDs that test oral fluids for the reasons discussed with respect to § 26.83(a). The procedures for conducting alcohol testing of oral fluids with an ASD incorporate the related requirements from 49 CFR Part 40 and have been added to the final rule to ensure that initial alcohol tests of oral fluids provide accurate and legally defensible test results.

The agency has added § 26.97(a) to specify the procedures that the collector must follow in using an ASD for testing oral fluids.

Section 26.97(a)(1) requires the collector to check the expiration date on the device and show it to the donor. Because some devices degrade during storage, this step is necessary to assure both the donor and the collector that the device can be expected to function properly.

Section 26.97(a)(2) requires the collector to open an individually wrapped or sealed package containing the device in the presence of the donor for the reasons discussed with respect to § 26.95(b)(1).

Section 26.97(a)(3) requires 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 must provide instructions for its proper use. The final rule requires 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 § 26.95(b)(1).

Section 26.97(a)(4) requires 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 is required to wear single-use examination or similar gloves while doing so and change them following each test. Section 26.97(a)(5) requires the collector to follow the manufacturer's instructions to ensure that the device has activated. The NRC has added the requirements in these sections to ensure that the collection is properly conducted. The requirement to use single-use examination gloves ensures that the collector and donor are protected from possible infection from exposure to body fluids.

The NRC added § 26.97(b) to specify the procedures that the collector must 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 because the device is dropped on the floor.

Section 26.97(b)(1) requires 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 final rule requires the second device to have been under the collector's control to ensure that the donor or another individual has no opportunity to substitute the new device with another that has been altered to provide a false negative test result. This provision is necessary to protect the integrity of the collection process.

Section 26.97(b)(2) requires the collector to record the reason for the new test. This requirement ensures that the information is available, should any questions arise with respect to the collection procedure in a review conducted under § 26.39 [Review process for fitness-for-duty policy violations] or legal proceedings.

Section 26.97(b)(3) requires 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 final rule requires the collector to offer the donor the choice of using the device for the reasons discussed with respect to

§ 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 enhances the efficiency of the collection procedure by ensuring that the second collection is conducted properly.

Section 26.97(b)(4) requires the collector to repeat the collection procedures outlined in § 26.97(a) for the second collection.

If the second collection attempt fails, § 26.97(c) directs the collector to use an EBT to perform the initial alcohol test instead. The final rule requires 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, § 26.97(d) instructs the collector to follow the device manufacturer's instructions for reading the result and show the result to the donor. The final rule prohibits 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 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. This paragraph also requires the collector to record the test result and document that an ASD was used to ensure that the information is available, should any questions arise with respect to the collection procedure in a review conducted under § 26.39 or legal proceedings.

To protect collectors and donors from any possible biohazards, the final rule adds § 26.97(e) 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.

Section 26.99 amends the requirements in former § 26.24(g) and the portion of Section 2.7(e)(1) in Appendix A to Part 26 that addressed cutoff levels for alcohol testing. The final rule amends the former requirements for consistency with a new approach to determining positive alcohol test results in § 26.103 [Determining a confirmed positive test result for alcohol]. The NRC adopted the new approach because some licensees have not taken appropriate action when a donor has obtained alcohol test results just below the 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, the final rule establishes new cutoff levels for alcohol testing in §§ 26.99 and 26.103 [Determining a confirmed positive test result for alcohol] that take into account the average rate at which individuals metabolize alcohol over time. In § 26.99(a), the agency decreased the cutoff level for the initial alcohol test result from 0.04 to 0.02 percent BAC and requires a confirmatory alcohol test if a donor's initial test result is 0.02 percent BAC or higher. In addition, § 26.99(b) requires the collector 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 can be calculated to determine whether a confirmatory test result is positive, in accordance with § 26.103 [Determining a confirmed positive test result for alcohol]. These changes to the initial alcohol test cutoff level and testing procedure are necessary to support the provisions of § 26.103, which 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 1 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 permits 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.

The NRC added this section to provide detailed procedures for conducting confirmatory breath alcohol tests. These procedures incorporate the related requirements from 49 CFR Part 40, which the NRC has added to the final rule to ensure that confirmatory breath alcohol tests provide accurate and legally defensible test results when using the EBTs that are required in § 26.91(b) [Acceptable evidential breath testing devices] and relying on one breath specimen for confirmatory testing, as is required in § 26.91(c).

Section 26.101(a) requires 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 final rule adds this requirement to reduce the possibility that alcohol metabolism will cause a confirmatory test to provide a result falling below the applicable cutoff level. Former Section 2.4(g)(18) in Appendix A to Part 26 did not require conducting a confirmatory test as soon as possible after obtaining a positive initial alcohol test result, although licensees follow this practice. However, the agency had added a 30-minute limit because some FFD program personnel may be tested under DOT procedures, as permitted in § 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 is unnecessary at licensees' and other entities' collection sites because licensees' and other entities' collection sites must have the capability to conduct confirmatory tests with an EBT, as required under § 26.87(a). Therefore, except in these unusual circumstances, licensees and other entities are expected to continue their current practice of conducting the confirmatory test immediately after a donor's initial test result is determined to be positive.

The NRC added § 26.101(b) to specify procedures for conducting a confirmatory alcohol test.

Sections 26.101(b)(1) and (b)(2) require the collector to conduct an air blank before beginning the confirmatory test and verify that the air blank reading is 0.00. These steps are necessary to ensure that the EBT is functioning properly before the test begins.

Section 26.101(b)(3) requires the collector to take the EBT out of service if a second air blank test reading is above 0.00. This 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.

The NRC has added § 26.101(b)(4) through (b)(7) 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 need for these steps is the same as for those discussed with respect to the related steps in § 26.95 [Conducting an initial test for alcohol using a breath specimen]. However, the final rule does 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 is necessary if any questions arise with respect to the collection procedure in a review conducted under § 26.39 [Review process for fitness-for-duty policy violations] or legal proceedings.

Section 26.101(c) requires 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 must rely on the result from the first successful collection in determining the confirmatory test result. As discussed under § 26.95(c), if the specified procedures are followed, relying on one breath specimen for the

initial test rather than the two required in the former rule increases the consistency of Part 26 collection procedures with those of other Federal agencies. This also reduces the time required for breath specimen collections without compromising the accuracy, validity, or reliability of the test results. This section also prohibits 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, required by former Section 2.4(g)(18) in Appendix A to Part 26, are no longer necessary because of the mandatory use of the EBTs specified in § 26.91(b). The change meets Goal 3 of this rulemaking to improve the efficiency of FFD programs.

Section 26.101(d) amends the portion of former Section 2.4(g)(18) in Appendix A of Part 26 that required using a different EBT to conduct the confirmatory alcohol test than used for initial alcohol testing. The final rule permits the use of the same EBT for both initial and confirmatory alcohol testing, instead of requiring the use of two different EBTs. The licensee or other entity must obtain one breath specimen for initial alcohol testing and one for confirmatory testing, if necessary, but is permitted to conduct both tests using the same EBT. The NRC has made this change because improvements in EBT technology assure that valid and reliable test results may be obtained from a single EBT if the specimen collection and quality assurance procedures in this part are followed. Reducing the number of breath specimens required for alcohol testing not only reduces the costs associated with alcohol testing, but also reduces the burden on donors that the collection process imposes. 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.

Section 26.103 amends the cutoff level for determining whether a confirmatory alcohol test result is positive, as specified in former § 26.24(g) and Section 2.7(f)(2) in Appendix A to

Part 26. This section establishes 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 § 26.99 [Determining the need for a confirmatory test for alcohol]. Section 26.103(a)(1) retains the 0.04 percent BAC in former § 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. Sections 26.103(a)(2) and (a)(3) 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 on confirmatory testing but indicate that the donor had a BAC of 0.04 percent or greater while in a work status or consumed alcohol while on duty. The cutoff levels and time periods in § 26.103(a)(2) and (a)(3) are based on 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 1 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 changes 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.

The NRC added § 26.103(b) 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 § 26.103(a). The final rule requires the collector to declare the test as negative because NHTSA has not thoroughly evaluated some of

the EBTs that licensees and other entities are permitted to use for confirmatory alcohol testing under the final rule 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 provides a reason to believe that the individual has been impaired while on duty. Therefore, the provision requires the licensee or other entity, after testing, to ensure that the donor's alcohol use is evaluated, a determination of fitness is performed, and the determination of fitness indicates 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. This change strengthens 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.

The NRC has deleted former Section 2.4(g)(19) in Appendix A to Part 26, which established requirements for collecting a blood specimen for alcohol testing, in its entirety because the final rule no longer permits blood testing for alcohol, at the donor's discretion, for the reasons discussed with respect to § 26.83(a).

Section 26.105 Preparing for urine collection.

This section is added to describe the preliminary steps for collecting a urine specimen for drug testing. For organizational clarity, this section reorganizes the requirements in former Section 2.4(g)(5) through (g)(7) in Appendix A to Part 26 by separating alcohol and urine specimen collection procedures into separate sections of the final rule. The section also establishes several new requirements that the agency has added to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant

Federal rules and guidelines.

Section 26.105(a) revises former Section 2.4(g)(5) in Appendix A to Part 26. The final rule retains the former requirement for 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. However, the final rule eliminates the references to blood and breath specimens in the former paragraph because the final rule no longer permits donors to request blood testing for alcohol. This paragraph also eliminates reference to breath specimens because the final rule presents requirements related to preparing for alcohol testing in a separate section (§ 26.93 [Determining the need for a confirmatory test for alcohol]) for organizational clarity.

The NRC added § 26.105(b) to require the donor to empty his or her pockets and display the items contained in them. The new requirement for the collector to examine the articles in the donor's pockets increases 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 rule requires the collector 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, this section requires 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

must secure the item and continue with the collection. The agency added these requirements to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, as well as Goal 3 to improve the effectiveness of FFD programs, by improving the ability of the collector to identify attempts to subvert the drug testing process. Adding the requirement for the donor to permit the collector to make this examination ensures that donors understand that they must cooperate with the examination.

Section 26.105(c) retains former Section 2.4(g)(6) in Appendix A to Part 26, which required the individual to be instructed to wash his or her hands prior to urination. The final rule makes two minor editorial changes to the former provision for clarity in the language of the final rule. The final rule clarifies that the collector is to instruct the donor to wash and dry his or her hands and replaces the term “individual” with the term “donor.”

Section 26.105(d) retains former Section 2.4(g)(7) in Appendix A to Part 26 and 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 final rule makes two minor editorial changes to the former provision for clarity in the language of the rule. The final rule replaces the term “collection site person” with the simpler term “collector” and the term “individual” with the term “donor.”

The NRC added § 26.105(e) 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 is not required. However, this practice 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 may attempt to subvert the testing process by selecting a kit that had been contaminated with a substance that would produce a positive, adulterated, substituted, or invalid 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 § 26.95(b)(1). This paragraph also prohibits the donor from taking collection kit materials (such as the specimen label) other than the collection container, into the private area used for urination. This prohibition ensures that a donor could not tamper with the other collection kit materials and thereby disrupt the chain of custody for the urine specimen.

This section is consistent with the related requirements of other Federal agencies and so meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, as well as Goal 3 to improve the effectiveness of FFD programs, by improving the ability of the collector to identify attempts to subvert the drug testing process. The final rule adds the new provision requiring the donor to permit the collector to make this examination in response to stakeholder requests at the public meetings discussed in the preamble to the proposed rule to ensure that donors understand that they must cooperate with the examination.

Section 26.107 Collecting a urine specimen.

Section 26.107 amends former Section 2.4(g)(8), (g)(9), and (g)(12) in Appendix A to Part 26 to update the rule's urine specimen collection procedures and incorporate advances in other relevant Federal rules and guidelines, consistent with Goal 1 of this rulemaking.

The NRC added § 26.107(a)(1) to specify the instructions that the collector is required to provide to the donor. This paragraph requires the collector to instruct the donor to go into the room or stall used for urination, provide a specimen of the quantity that the licensee or other entity has predetermined, refrain from flushing the toilet, and return with the specimen as soon as the donor has completed the void. The final rule requires the collector to provide these instructions to the donor so that the donor understands his or her responsibilities with respect to

the urine collection procedure. In addition, the instructions are necessary to implement other provisions of the final rule. For example, the quantity of urine that the collector instructs the donor to provide is based on the requirements of the licensee's or other entity's drug testing program, as discussed with respect to § 26.109 [Urine specimen quantity]. The collector instructs 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 § 26.109(c). The collector must 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 cools and its temperature falls below the acceptable specimen temperature range specified in § 26.111(b).

Section 26.107(a)(1) further amends former Section 2.4(g)(8) in Appendix A to Part 26. The former provision stated that the individual may provide his or her urine specimen in the privacy of a stall or otherwise partitioned area that protects individual privacy. For clarity, this paragraph replaces "may" in the former rule with "shall" to indicate that the area in which the donor will urinate must provide for individual privacy. The final rule also adds an exception to the former requirement for privacy in the case of a directly observed collection. The agency made this change for greater accuracy in the rule language because the requirement for individual privacy does not apply in the case of a directly observed collection, as discussed with respect to § 26.115 [Collecting a urine specimen under direct observation].

The NRC added § 26.107(a)(2) to further emphasize the requirement in former Section 2.4(g)(8) in Appendix A to Part 26 that donors must be afforded individual privacy when providing a urine specimen. The new paragraph requires 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 former requirement for individual privacy has been compromised, the experience of other Federal agencies has indicated that such emphasis is necessary.

Section 26.107(a)(3) permits the collector to set a reasonable time limit for the donor to void. Rather than establishing a specific time limit, the final rule permits 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. In § 26.85(a), the rule specifies new training and qualification requirements to ensure that collectors are able to exercise professional judgment appropriately. At the public meetings discussed in the preamble to the proposed rule, 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 new paragraph clarifies that collectors have the authority to set a reasonable time limit for voiding. In addition, this paragraph increases the consistency of Part 26 with the procedures implemented by other Federal agencies in accordance with Goal 1 of this rulemaking.

Section 26.107(b) amends former Section 2.4(g)(9) in Appendix A to Part 26. The former provision required the collector to note any unusual behavior or appearance in the permanent record book and on the custody-and-control form. This section clarifies the intent of the former requirement, which raised implementation questions from licensees, by specifying that the collector must pay careful attention to the donor during the collection process so that the collector can note any conduct that may indicate an attempt to substitute or tamper with the specimen. This section also provides examples of the types of behavior that may indicate a subversion attempt and requires the collector to contact FFD program management if he or she observes such behavior. This section requires FFD program management to determine whether a directly observed collection is necessary under § 26.115 [Collecting a urine specimen under direct observation].

The NRC added § 26.107(c) to specify the actions to be taken by the collector and

donor to complete the specimen collection procedure. The first sentence of § 26.107(c) retains the instruction in former Section 2.4(g)(12) in Appendix A to Part 26 that prohibits the donor from washing his or her hands until the specimen has been delivered to the collector. This paragraph also adds a requirement for the collector to inspect the private area for any evidence of a subversion attempt prior to flushing the toilet. This additional requirement is consistent with existing industry practices and the procedures of other Federal agencies. It is intended to increase the likelihood of detecting subversion attempts if the donor leaves any physical evidence in the toilet bowl or private area where the donor voided, which could include, but is not 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.

Section 26.109 amends former Section 2.4(g)(11) in Appendix A to Part 26. The former provision established 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. The final rule reduces to 30 mL the basic quantity of urine to be collected.

Section 26.109(a) introduces a new term “the predetermined quantity.” The licensee or other entity establishes a predetermined quantity of urine that each donor is requested to provide, depending on the characteristics of the licensee’s or other entity’s testing program. The final rule requires the predetermined quantity to include at least 30 mL of urine, but licensees and other entities may request a larger quantity of urine if—

The specimen will be initially tested at a licensee testing facility;

Testing will be conducted for additional drugs beyond those required in § 26.31(d)(1);

Split specimen procedures will be followed; or

The licensee’s or other entity’s program includes some combination of these

characteristics.

The NRC has reduced the 60-mL quantity that was required in former Section 2.4(g)(11) in Appendix A to Part 26 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 § 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 is no longer 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 § 26.31(d)(1), as well as retesting of the specimen, if required.

Section 26.109(a) also specifies the additional quantity of urine, above the basic 30 mL, to be collected when the testing program follows split specimen procedures. The rule requires licensees and other entities 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 § 26.113(b), the final rule replaces the terms, "primary specimen" and "split specimen," in the former 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 is 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 § 26.31(d)(1), then the predetermined quantity for this testing program is 45 mL (30 mL for basic testing + 15 mL for the split specimen). The predetermined quantity must be larger than 45 mL if the testing program also includes initial

tests at a licensee testing facility and testing for additional drugs.

Section 26.109(a) also permits licensees and other entities to include in the predetermined quantity the additional amount of urine that is necessary to support testing for additional drugs beyond those specified in § 26.31(d)(1). Licensees and other entities must 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 consists 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 consists of the 30-mL basic quantity plus 15 mL for the split specimen plus the additional amount required by the licensee testing facility and HHS-certified laboratory to test for the additional drugs.

Section 26.109(a) also permits 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 there. 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 other drugs or follow split specimen procedures. In this program, the predetermined quantity that collectors must 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 may 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 may be larger than

55 mL.

The final rule adds § 26.109(b) 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 § 26.31(d)(1). The 30-mL quantity also ensures 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 § 26.165(b). Therefore, the 30-mL basic quantity is necessary to achieve the NRC's drug-testing objectives, although it is insufficient to permit testing for additional drugs, initial testing at licensee testing facilities, or splitting the specimen, which this part does not require.

Section 26.109(b)(1) amends the portions of former Section 2.4(g)(11) in Appendix A to Part 26 that prescribed collector actions if a donor provides an insufficient specimen. The final rule requires 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 required under the former rule. The NRC made this change 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, this paragraph establishes a limit on the amount of liquid that the individual is 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. Although the limit of 24 ounces of water over a 3-hour period in the proposed rule is the same limit imposed in the HHS Guidelines, the NRC raised the limit in the final rule to 40 ounces over a 3-hour period for consistency with the DOT limit, in response to

public comment. This limit continues to be conservative 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 who are taking some medications, would not be placed at risk. The final rule retains the former requirement in Section 2.4(g)(11) in Appendix A to Part 26 to collect successive specimens in separate containers.

The NRC added § 26.109(b)(2) 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 requirement reduces 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.

Section 26.109(b)(2) also specifies 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. Imposing 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 is 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.

Section 26.109(b)(2) also requires 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 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. However, if the subsequent specimen is equal to or greater than the licensee's or other entity's predetermined quantity, the licensee or other entity is permitted to follow the FFD program's normal testing procedures. Following normal testing

procedures in this instance is permissible because there is 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.

The agency added § 26.109(b)(3) 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 § 26.119 [Determining "shy" bladder]. Requirements for implementing "shy bladder" procedures are contained in that section.

The NRC added § 26.109(b)(4) to establish additional requirements for specimen collections when a donor provides a specimen of less than 30 mL, as follows:

This section eliminates the requirement in former 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 final rule prohibits the practice of combining specimens to ensure that successive specimens neither contaminate nor dilute a specimen that will be tested. In addition, the prohibition increases the consistency of Part 26 with the related requirements of other Federal agencies (Goal 1 of this rulemaking).

Section 26.109(b)(4) also requires 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 may include, but are not 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 voiding, 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 final rule requires the collector to discard specimens of less than 30 mL when there is no reason to believe that the specimens have been subject to tampering because they are not used for testing and there is no reason to retain them.

If the collector suspects that a specimen has been altered and the suspect specimen is equal to or greater than 15 mL, the rule requires the collector to forward the suspect specimen to the HHS-certified laboratory for testing, consistent with former 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 is insufficient to support retesting of the specimen at the donor's request. When 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 takes precedence over the donor'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, provide clear evidence that a donor has tampered with the specimen and thereby attempted to subvert the testing process.

This section also amends former Section 2.4(g)(17) in Appendix A to Part 26. The former provision required a directly observed collection whenever there is a reason to believe that a donor has or may attempt to alter a specimen. The amended provision requires the collector to contact FFD program management to determine whether a directly observed collection is required, but does not require a directly observed collection in every circumstance. At the public meetings discussed in the preamble to the proposed rule, the stakeholders requested flexibility in the decision to collect another specimen under direct observation. They noted that numerous instances have occurred 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 establishes a clear motive for an alleged attempt to tamper with a specimen and adds further evidence supporting the imposition of sanctions on the donor for attempting to subvert the testing process. However, the NRC believes 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 final rule permits FFD program management to determine whether an additional specimen collection under direct observation must be conducted. The agency has made this change to meet Goal 3 of this rulemaking to improve the efficiency of FFD programs, by reducing the number of directly observed collections required under the rule.

Section 26.111 Checking the acceptability of the urine specimen.

Section 26.111 amends former requirements for assessing specimen validity at the collection site, which appeared in Section 2.4(g)(13) through (g)(17) in Appendix A to Part 26. In general, the NRC has made changes in this section to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. In addition, the NRC changed the heading of this section from “Checking the validity of the urine specimen” in the proposed rule to “Checking the acceptability of the urine specimen,” in response to a public comment which noted that “acceptability” more accurately characterizes the purpose of the requirements in this section.

Section 26.111(a) amends former Section 2.4(g)(13) in Appendix A to Part 26. The former provision required the collector to measure the temperature of the specimen

immediately after the urine specimen is collected. The new provision requires the collector to measure the temperature of any specimen that is 15 mL or more. The final rule does not mandate measuring the temperature of smaller specimens because the collector is required to discard them, as discussed with respect to § 26.109(b)(4). This paragraph also replaces former Section 2.4(g)(14) in Appendix A to Part 26, which established the acceptable specimen temperature range and required conducting a second specimen collection under direct observation if a specimen's temperature falls outside the acceptable range. The final rule increases the range of acceptable specimen temperatures from 90.5°F–99.8°F in the former provision to 90°F–100°F for consistency with the temperature range specified in the HHS Guidelines. The wider acceptable temperature range provides increased protection against false low or false high temperature readings and, therefore, protects donors from the imposition of sanctions based on inaccurate specimen temperature readings. The portion of former Section 2.4(g)(14) that specified collector actions if there is a reason to believe that the individual may have tampered with the specimen has been moved to § 26.111(d) for organizational clarity.

In response to a public comment, the final rule eliminates the requirement in § 26.111(a), which appeared in both the former and proposed rules, for the collector to offer the donor an opportunity to provide a measurement of body temperature. In addition, the final rule deletes § 26.111(b) in the proposed rule entirely and has renumbered the paragraphs in this section accordingly. The NRC has made these changes in response to public comments, which reported that DOT's experience indicates that there are often discrepancies when comparing the temperature provided by a specimen container temperature strip and that provided by a device that measures body temperature. Further, with the increase in the range of acceptable specimen temperatures, as discussed with respect to § 26.111(a), a measurement of body temperature is less useful to counter a reason to believe that the donor

has altered the specimen (e.g., humans who have a body temperature at or below 90 °F would be suffering from severe hypothermia). Therefore, eliminating the opportunity for a donor to provide a measure of body temperature in this paragraph meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.111(b) amends former Section 2.4(g)(15) in Appendix A to Part 26. The former provision required the collector to inspect the specimen's color, determine whether there were any signs of contaminants, and record any unusual findings in the permanent record book. The final rule amends this provision by deleting reference to the permanent record book and requiring the collector to use the custody-and-control form to record this information. The NRC has made this change because the final rule no longer requires 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 final rule also makes minor editorial revisions to the former provision by incorporating the related language from the HHS Guidelines. The agency made these changes to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with the regulations of other Federal agencies.

Section 26.111(c) replaces and amends the first sentence of former Section 2.4(g)(14) in Appendix A to Part 26. The former provision required a second specimen to be collected under direct observation if the temperature of the first specimen submitted by a donor fell outside of the acceptable specimen temperature range. The final rule eliminates 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 new provision requires 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 on observed donor behavior, the specimen temperature, unusual specimen characteristics, or other observations. The FFD program

manager, at his or her discretion, may 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 final rule permits the licensee or other entity to impose the sanctions for a subversion attempt in § 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 rule permits a 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 is collected under direct observation provide additional evidence that the donor attempted to tamper with his or her first specimen to hide drug use. The NRC has made this change in response to stakeholder requests, for the reasons discussed with respect to proposed § 26.109(b)(4).

The NRC also added permission in § 26.111(c) for a donor to volunteer to submit another specimen under direct observation to counter any reason to believe that he or she may have altered the first specimen. The agency added this permission in response to a public comment suggesting this change and because it is consistent with Goal 7 of the rulemaking to protect donor's rights (including due process) under the rule.

Section 26.111(d) replaces and revises former Section 2.4(g)(16) in Appendix A to Part 26. The former provision required forwarding all urine specimens that are suspected of being adulterated or diluted to the HHS-certified laboratory for testing. The final rule adds a third reason, suspicion that a specimen has been substituted, for forwarding a specimen to the HHS-certified laboratory. As discussed with respect to § 26.31(d)(3)(i), substitution entails replacing a valid urine specimen with a drug-free specimen. The NRC has made this change

for consistency with the addition of substitution to the final rule as another method of attempting to subvert the testing process for which licensees and other entities are required to impose sanctions, as discussed with respect to § 26.75(b). This paragraph also adds a provision that specifically prohibits testing any suspect specimen at a licensee testing facility 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 § 26.161(g)). Only suspect specimens of 15 mL or more must be sent for testing, rather than all specimens. The final rule establishes this lower limit on specimen quantity to ensure that there is sufficient urine available for the HHS-certified laboratory to conduct all of the validity and drug tests on the specimen that are required under this part. In response to a comment, this paragraph of the final rule also adds a requirement to send specimens of 15 mL or more, collected under direct observation in accordance with § 26.111(c), to an HHS-certified laboratory for initial and confirmatory testing.

Section 26.111(e) requires collectors and the HHS-certified laboratory to preserve as much of a suspect specimen as possible. The NRC has added this requirement to provide increased assurance that a sufficient quantity of urine is 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.

The agency also added § 26.111(f) to inform donors and collectors of the characteristics of a specimen that is acceptable for testing at an HHS-certified laboratory. This paragraph incorporates the related provision from the HHS Guidelines.

26.113 Splitting the urine specimen.

Section 26.113 updates former Sections 2.4(g)(20) and 2.7(j) in Appendix A to Part 26. This section amends collection site procedures for split specimens in the former rule and groups them together in one section within the final rule for organizational clarity.

Section 26.113(a) of the final rule revises the same provision in the proposed rule, in that the NRC has deleted the phrase “who are subject to this part” to provide additional clarity to the language of the rule, in response to public comment. The NRC deleted this phrase because not all of the licensees and entities who are subject to Part 26 are required to meet the requirements of this section.

For organizational clarity, the NRC has added § 26.113(b) to group together in one paragraph the steps that the collector and donor must follow for the split specimen collection procedure. These steps were embedded in former Section 2.4(g)(20) and portions of Section 2.7(j) in Appendix A to Part 26. The final rule also replaces the terminology used in the former rule that referred to the split specimen as an “aliquot,” and uses the terms, “Bottle A” and “Bottle B,” to refer to the primary and split specimen, respectively. The agency made these changes for increased clarity in the language of the rule and consistency with the terminology used in other relevant Federal rules and guidelines.

In response to a public comment, the NRC revised proposed § 26.113(b)(1) to delete the option of using a specimen bottle to collect a urine specimen to eliminate the possibility of problems arising from collecting urine in two different types of containers. The final rule retains the requirement for the collector to instruct the donor to void into a specimen container to clarify that the donor is not required to divide a specimen into Bottle A and Bottle B while urinating. This paragraph incorporates the related provision in the HHS Guidelines.

Section 26.113(b)(2) amends the portions of former Section 2.7(j) in Appendix A to Part 26 that specified the amount of urine to be poured into the split specimen bottles. The rule

replaces the implied requirements in the second and third sentences of Section 2.4(j), which referred to the split specimens as “halves” of the specimen that was collected, with updated requirements that are consistent with those established in § 26.109 and the related provisions in the HHS Guidelines. This paragraph requires the collector to ensure that Bottle A contains 30 mL and that Bottle B contains a minimum of 15 mL of urine. As discussed with respect to § 26.109 [Urine specimen quantity], advances in urine testing technologies since the agency first promulgated Part 26 permit a reduction in the quantity of urine that must be collected from donors in order to conduct the testing this part requires. Therefore, 30 mL of urine is now a sufficient quantity for conducting all of the testing that may be required under this part and 15 mL is sufficient for conducting testing of the specimen in Bottle B.

In response to public comment, the NRC has revised this paragraph in the final rule to more clearly specify that the specimen in Bottle A must be used for drug and validity testing even if there is less than 15 mL of urine available for Bottle B. The agency added this clarification to the final 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. Following this practice would reduce the efficiency of FFD programs and unnecessarily increase the burden on donors who are subject to testing. The final rule incorporates this clarification from the HHS Guidelines to ensure that Part 26 programs do not adopt this inefficient and burdensome practice.

Section 26.113(b)(3) retains the portion of former 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.

The NRC added § 26.113(c) to establish priorities for using the specimen that has been

collected. The paragraph permits 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 § 26.31(d)(1), but only if the donor has provided a specimen of at least the predetermined quantity, as discussed with respect to § 26.109 [Urine specimen quantity]. As discussed with respect to § 26.113(b)(2), the final rule requires 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 final rule permits the remaining amount of urine to be subject to such testing. However, if the donor has provided only 45 mL of urine, the final rule requires 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 final rule establishes this priority 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 is also consistent with the principle that is established in the last sentences of §§ 26.135(b) and 26.165(a)(4) that control over testing of the specimen contained in Bottle B resides with the donor.

Section 26.115 Collecting a urine specimen under direct observation.

Section 26.115 groups together in one section the former rule's requirements that apply to collecting a urine specimen under direct observation. The NRC has made this organizational change because requirements that address this topic were dispersed throughout the former rule. This section also incorporates more detailed procedures for collecting specimens under direct observation that are based on 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 agency has made these changes to increase the likelihood of detecting attempts to subvert the testing process and increase the effectiveness of directly observed collections in assuring that a valid specimen is obtained from the donor.

Section 26.115(a) amends and combines former Section 2.4(f), 2.4(g)(17), and (g)(25) in Appendix A to Part 26. The former provisions established requirements for collecting a urine specimen under direct observation. This paragraph of the final rule assigns responsibility for approving a directly observed collection to the MRO or FFD program manager, rather than a "higher level supervisor" of the collector, as stated in former Section 2.4(b)(25) in Appendix A to Part 26. This change ensures that 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, makes the decision to conduct a directly observed collection. The change is also consistent with revised requirements in the HHS Guidelines related to who may authorize a directly observed collection.

The final rule also lists the circumstances that constitute a reason to believe that a donor may dilute, substitute, adulterate, or otherwise alter a specimen, and that warrant the invasion of individual privacy associated with a directly observed collection.

Section 26.115(a)(1) amends former Section 2.4(f)(2) in Appendix A to Part 26, which stated that a directly observed collection may be performed if the last urine specimen provided by the donor yielded specific gravity and creatinine concentration results that were inconsistent with normal human urine. The new paragraph amends the former provision in several ways.

First, the final rule eliminates the limitation in the former 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 final rule permits 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 change is consistent with § 26.75(b), which requires 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 § 26.75(b) requires 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 are not subject to further testing under the rule. However, instances may arise in which a licensee or other entity is aware that an individual engaged in a subversion attempt under a drug testing program that the NRC does not regulate. If the licensee or other entity is considering granting authorization under Part 26 to the individual, then a directly observed collection is warranted to ensure that the donor does not have an opportunity to tamper with the specimen and, therefore, that drug test results will be accurate. The amended language of the new provision permits collecting a specimen under direct observation in these circumstances.

Second, the final rule updates the former provision by replacing the specific gravity and creatinine concentration values in the former 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.” The NRC made this change for consistency with the addition of more detailed requirements for validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). Section 26.161 [Cutoff levels for validity testing] specifies the cutoff concentrations and specimen characteristics that require the HHS-laboratory to report a specimen as substituted, adulterated, or invalid. Section 26.185 [Determining a fitness-for-duty

policy violation] specifies the requirements for the MRO's review of these test results.

Section 26.115(a)(2) combines and updates former Sections 2.4(f)(1) and 2.4(g)(14) in Appendix A to Part 26. The former provisions stated that the presentation of a specimen that falls outside of the required temperature range is sufficient grounds to conduct a directly observed collection. The new paragraph retains the requirement in former Section 2.4(f)(1) in Appendix A to Part 26, which specified that a directly observed collection may be conducted at any time the specimen's temperature falls outside of the required temperature range. However, the final rule deletes the provisions of the proposed rule that addressed measuring the donor's body temperature for the reasons discussed with respect to § 26.111(a).

Section 26.115(a)(3) updates former Section 2.4(f)(3) in Appendix A to Part 26. The former provision permitted a directly observed collection if a collector observed donor conduct that clearly and unequivocally demonstrates an attempt by the donor to substitute the specimen. The final rule adds 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 in the final rule for ensuring specimen validity, as discussed with respect to § 26.31(d)(3)(i). As discussed with respect to § 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 § 26.87(e)(1)) discolors the specimen.

Section 26.115(a)(4) updates former Section 2.4(f)(4) in Appendix A to Part 26. The former provision permitted directly observed collections if a donor had previously been determined to have engaged in substance abuse and the specimen was being collected as part

of a rehabilitation program and/or pre-access testing following a confirmed positive test result. This paragraph updates the former requirement by adding a cross-reference to § 26.69 [Authorization with potentially disqualifying fitness-for-duty information], which establishes requirements for granting or maintaining the authorization of an individual about whom potentially disqualifying FFD information has been discovered or disclosed. Several provisions in § 26.69 [Authorization with potentially disqualifying fitness-for-duty information] permit or require directly observed collections, including § 26.69(b)(5), which requires 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, this paragraph replaces the former requirement with a cross-reference to § 26.69, rather than repeat the applicable requirements in this section.

Section 26.115(b) amends the requirement in former 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 § 26.115(a). The NRC has added the second sentence of this paragraph 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 new requirement ensures 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. Positive, adulterated, substituted, or invalid test results from a specimen collected under direct observation 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 ensures that test results from the specimen provide relevant and useful information. The requirement is also consistent with those of other relevant Federal rules and guidelines.

The agency added § 26.115(c) 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. The final rule includes this requirement 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 meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 by ensuring that the donor is aware of the concern that has initiated the collection. This paragraph also meets Goal 1 of this rulemaking by improving consistency with the requirements of other relevant Federal rules and guidelines.

The NRC added § 26.115(d) to establish recordkeeping requirements related to the directly observed collection. This provision requires the collector to record on the specimen's custody-and-control form that the specimen was collected under direct observation and the reason(s) for the directly observed collection. This requirement ensures 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 is required under § 26.185 [Determining a fitness-for-duty policy violation]. This information is important in an MRO's decision to request the laboratory to test a specimen that appeared to have been diluted, as permitted under

§ 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. Positive, adulterated, substituted, or invalid test results from the dilute specimen and the presence of the same drugs or drug metabolites in the specimen collected under direct observation provide evidence that the donor diluted the first specimen in an attempt to mask drug use. This section is also consistent with the requirements of other relevant Federal rules and guidelines.

Section 26.115(e) retains and combines the former requirements in Sections 1.2, 2.4(b), 2.4(g)(14), (g)(17), and (g)(25) in Appendix A to Part 26. These provisions required that the individual who observes the specimen collection must be of the same gender as the donor. Consistent with the former requirements, the final rule permits 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 § 26.115(f). The final rule combines the former requirements in this paragraph for organizational clarity.

The NRC added § 26.115(f) to specify the procedures that must be followed in conducting a directly observed collection 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 agency made these changes to increase the likelihood of detecting 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.

The NRC added § 26.115(f)(1) 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 requirement ensures that the observer is able to detect the use of an anatomically correct urine delivery device.

The agency added § 26.115(f)(2) to specify the action to be observed during the collection. This paragraph is consistent with the requirements of other Federal agencies and is intended to ensure that the urine specimen is obtained from the donor's body.

The rule adds § 26.115(f)(3) to prohibit an observer who is not the collector from touching the specimen container. The new provision is 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.

The new § 26.115(f)(4) requires the collector to record the observer's name on the custody-and-control form if the observer is not the collector. This mandate is 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.

The NRC added § 26.115(g) to clarify that a donor's refusal to participate in the directly observed collection constitutes a refusal to test and, therefore, is considered to be an act to subvert the testing process under § 26.75(b). Former Section 2.4(j) in Appendix A to Part 26 required the collector to inform the MRO, and the MRO to inform licensee management, if a donor failed 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 former requirement did 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 former rule did not require the licensee or other entity to impose sanctions on a donor for refusing to be tested. Therefore, the final rule adds a provision that both clarifies the NRC's original intent by stating that a refusal to participate in a directly observed collection constitutes a refusal to test and updates the former requirement by adding a cross-reference to the sanction of permanent denial of authorization that is required under § 26.75(b).

The agency added § 26.115(h) to specify the actions that a collector must take if a

directly observed collection was required but not performed. The collector must report the omission to the FFD program manager or designee, who ensures 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 are 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 increases 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 reduces the concentrations of drugs, drug metabolites, or alcohol in the donor's specimens, the final rule requires a directly observed collection to be performed immediately. This section uses 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 requirement increases consistency with the related requirements of other Federal agencies and is intended to provide instructions for correcting an oversight that the former rule did not address.

Section 26.117 Preparing urine specimens for storage and shipping.

A new § 26.117 reorganizes and presents together in one section former 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. The NRC made this organizational change because requirements that address these topics were dispersed throughout the former rule and grouping them together in a single section in the final rule makes them easier to locate.

Section 26.117(a) amends former Section 2.4(g)(20) in Appendix A to Part 26, which required the donor and collector to maintain visual contact with specimens until they were sealed and labeled. The final rule eliminates reference to blood specimens because donors are no longer permitted to request blood testing for alcohol under the final rule, as discussed with respect to § 26.83(a). The new paragraph also amends the requirements in the second sentence of the former provision. For organizational clarify, the final rule moves to § 26.113 [Splitting the urine specimen] procedural requirements for observing the splitting of a specimen and sealing the split specimen bottles. However, this provision broadens the former requirement, which addressed 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 requirement is 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 final rule requires the donor to observe these actions 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.

Section 26.117(b) retains former Section 2.4(g)(21) in Appendix A to Part 26. This provision 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.

Section 26.117(c) retains the meaning of former Section 2.4(g)(22) in Appendix A to Part 26. This provision establishes requirements for labeling and sealing the specimen(s), but the final rule splits the former requirement into several sentences for increased clarity in the language of the provision.

For organizational clarity, § 26.117(d) retains and combines former Section 2.4(g)(23) and 2.4(g)(23)(i) in Appendix A to Part 26. These provisions required the donor to certify that

the specimen was collected from him or her. However, the final rule deletes former Section 2.4(g)(23)(ii), which required the donor to have an opportunity to list on the custody-and-control form any medications he or she had taken within the past 30 days for the reasons discussed with respect to § 26.89(b)(3).

The final rule deletes former Section 2.4(g)(24) in Appendix A to Part 26, which required the collector to enter into the permanent record book all information identifying the specimen. The agency eliminated this requirement because the final rule no longer requires 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 are permitted to use other means of tracking specimen identity, including, but not limited to, bar coding.

Section 26.117(e) amends former Section 2.4(g)(26) in Appendix A to Part 26. The former provision required 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 final rule eliminates reference to the aliquot and split sample in the former section 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. This section retains the former requirement for the collector to certify proper completion of the collection.

Section 26.117(f) amends former Section 2.4(g)(27) in Appendix A to Part 26. The former provision stated 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 final rule replaces the first sentence of the former provision, which stated 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 change improves 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. This section retains the second sentence of the former provision.

Section 26.117(g) retains former Section 2.4(g)(28) in Appendix A to Part 26. This provision 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 final rule makes minor editorial changes to some of the terminology used in the former section for consistency with the terminology used throughout the final rule, as discussed with respect to § 26.5 [Definitions], but retains the intended meaning of the former requirements.

Section 26.117(h) retains the requirements in former Section 2.4(c)(2) in Appendix A to Part 26 related to maintaining specimen security until the specimens are sent from the collection site to the licensee testing facility or the HHS-certified laboratory for testing. For organizational clarity, the NRC moved the former paragraph to this section of the final rule because requirements for maintaining specimen security apply at this point in the specimen collection process. Likewise, the agency has moved the portion of the former section that applies to situations in which it is impractical to maintain continuous physical security of a collection site to § 26.87(f)(5) because § 26.87(f) addresses those circumstances.

Section 26.117(i) updates the specimen packaging requirements in former Section 2.7(i) in Appendix A to Part 26 by replacing the former section with the related provision from the HHS Guidelines. For organizational clarity, the rule moves § 26.117(j) the first sentence of the former section, which directs collection site personnel to arrange to transfer the specimens to the licensee testing facility or HHS-certified laboratory. Section 26.117(j) addresses transfer

and storage requirements, while § 26.117(i) addresses packaging requirements. This section also eliminates the initial phrases in the second sentence of the former provision, which listed the conditions under which specimens were 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 are redundant with other portions of the final rule. For organizational clarity, the rule moves new requirements related to transferring specimens from a licensee testing facility to an HHS-certified laboratory for further testing to § 26.129(g) in Subpart F [Licensee Testing Facilities]. The final rule also eliminates the third sentence of the former section, which required the collector to sign and date the tape used to seal the container. The NRC eliminated this requirement because licensees and other entities now transfer specimens using courier services who offer other means of tracking the sender and the date that a container of specimens is shipped. Program experience has shown these other means to be equally effective. This new section retains the intended meaning of the former 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 the preamble to the proposed rule, the final rule adds shipping bags to the former set of examples of acceptable shipping containers that protect the specimens from damage. Also at the request of stakeholders, the final rule deletes the last sentence of the former section, which required the collector to ensure that chain-of-custody documents were attached to the container used to ship the specimens to the licensee testing facility or laboratory. The stakeholders requested this change because their practice is to seal a specimen’s 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, adopts this change.

Section 26.117(j) amends and combines the first sentence of former Section 2.4(i) in

Appendix A to Part 26 with the requirements applicable to the short-term storage of specimens at collection sites in former Section 2.7(c) in Appendix A to Part 26. The NRC moved to this section the first sentence of former Section 2.4(i) in Appendix A to Part 26 for the reasons discussed with respect to § 26.117(i). Under this section, as a result of advances in testing technologies, the rule no longer requires short-term refrigerated storage of specimens within 6 hours of collection. However, the final rule continues to require licensees and other entities to protect specimens from any conditions that could cause specimen degradation. Collection site personnel are 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 final rule also requires 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 final rule establishes 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.

Section 26.117(k) amends the portions of former Section 2.4(h) in Appendix A to Part 26 that required a specimen's custody-and-control form to identify every individual in the chain of custody. The final rule does not require couriers to meet the requirements in former Section 2.4(h), which stated 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 are not required to meet these requirements because custody-and-control forms for individual specimens are packaged inside the shipping container, where they are inaccessible to couriers, so that it is impractical to expect them to sign the forms when handling the specimen shipping containers. This new paragraph codifies licensees' and other entities' practice of relying on 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 final rule also eliminates the former 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.

The agency has adapted a new § 26.119 from the DOT Procedures at 49 CFR 40.193 [What happens when an employee does not provide a sufficient amount of urine for a drug test?] to specify procedures for determining whether a donor who does not provide a urine specimen of 30 mL within the 3 hours that is permitted for a specimen collection is refusing to test or has a medical reason for being unable to provide the required 30 mL specimen. This new section responds to stakeholder requests during public meetings discussed in the preamble to the proposed rule. The stakeholders reported that some donors have had difficulty providing the minimum 60 mL of urine required in former Section 2.4(g)(11) for medical reasons, but the former rule did not establish procedures for handling such circumstances. As a result, some FFD programs have adopted the DOT “shy bladder” procedures, but stakeholders preferred that the final 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 final rule because § 26.109 [Urine specimen quantity] reduces the minimum quantity of urine required from 60 mL in the former rule to 30 mL. However, because some donors’ medical problems may also interfere with their ability to provide 30 mL of urine, the final

rule incorporates the DOT procedures. These procedures are intended to protect the due process rights of individuals who are subject to Part 26. That is, this section establishes 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 is authorized to devise alternative methods of drug testing, if it appears that the donor's medical problem prevents him or her from being able to provide sufficient urine for drug testing in future tests.

The agency has added § 26.119(a) 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 rule permits the MRO to perform the evaluation if the MRO possesses the appropriate expertise. If not, the rule requires the MRO to review the qualifications of the physician and agree to the selection of that physician. These requirements for the physician who performs the evaluation to be qualified in the relevant medical issues ensure that the results of the evaluation are valid.

This section also requires that the evaluation must be completed within 5 calendar days of the unsuccessful collection. The agency has established the time limit of 5 calendar days as a trade off between the need 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. DOT's experience indicates that 5 days is sufficient to complete the evaluation.

The final rule adds § 26.119(b) 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. Sections 26.119(b)(1) and (b)(2) 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 requirements ensure that the evaluating physician understands the context in which he or she is being asked to perform the evaluation. Section 26.119(b)(3) also requires the MRO to inform the physician that he or she must agree to follow the procedures specified in § 26.119(c) through (f) if he or she performs the evaluation. This requirement ensures that the physician understands and consents to follow the procedures specified in this section.

The NRC added § 26.119(c) to describe the conclusions that the physician must provide to the MRO following the evaluation. Under § 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 § 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 final rule limits the physician's conclusions to one of these two alternatives 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.

The agency added § 26.119(d) to define the physical and psychological conditions that constitute a medical condition that could have precluded the donor from providing a 30-mL specimen as well as to provide examples of conditions that do not constitute a legitimate medical condition. Legitimate medical conditions 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 are examples of conditions that could not be considered legitimate medical conditions. The final rule adds this section to provide necessary guidance to the evaluating physician.

The final rule adds § 26.119(e) 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 provides this written statement. The written statement is necessary to communicate the results of the evaluation and create a record of it, should any question arise later with respect to the determination.

This section also requires that the physician must provide only the information that is necessary to support the physician's conclusion. The NRC has added this requirement to protect the donor's privacy by ensuring that the physician documents only the medical information that is necessary to support the determination.

The NRC added § 26.119(f) to require the physician to inform the MRO, in the written statement, whether any medical condition that may be identified also precludes the donor from providing specimens of 30 mL or more in future collections. This information is necessary for the MRO to determine whether to implement alternative methods of drug testing for the donor, as required under § 26.119(g)(3).

The agency added § 26.119(g) to prescribe the actions that the MRO must take based on the results of the evaluation, as follows:

Section 26.119(g)(1) requires 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 does not impose sanctions on the donor because the donor had not violated the FFD policy by refusing to test.

Section 26.119(g)(2) requires 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 imposes the sanction of a permanent denial of authorization for an attempt to subvert the

testing process, as required under § 26.75(b).

Section 26.119(g)(3) requires the MRO to devise an alternative method of collecting specimens for drug testing, if the donor's medical condition, over the long-term, consistently prevents the donor from providing urine specimens of 30 mL or more. For example, the provision permits 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 is scientifically defensible and forensically sound. The section grants flexibility to the MRO in exercising his or her professional judgment in determining an alternative method of conducting drug testing, rather than establishing detailed requirements that may not appropriately address the range of possible medical conditions that could arise.

Subpart F—Licensee Testing Facilities.

In this subpart, the final rule replaces two terms used in the proposed rule in response to public comments. These language changes affect numerous sections within Subpart F. First, one public comment addressed a proposed provision in § 26.137(b) [Performance testing and quality control requirements for validity screening tests] that permitted licensee testing facilities to use validity screening tests approved by the U.S. Food and Drug Administration (FDA). The NRC has eliminated both the requirement and the use of the term "device" with respect to validity screening testing because the FDA is not responsible for approving validity screening devices. The final rule has replaced the term "device" in "validity screening device" with the term "test" throughout Subpart F. Second, several public comments addressed the use of the term "non-negative" to refer to drug and validity test results and requested that the NRC eliminate the term from the final rule and instead use a more familiar term such as "positive" test result. Throughout Subpart F, the NRC has replaced the term "non-negative" with a new

term to address validity screening and initial validity testing results from a licensee testing facility that indicate that a specimen may be adulterated, substituted, dilute, or invalid. The new term used for these validity testing results is "questionable validity." The NRC has added a definition for "questionable validity" to § 26.5 [Definitions]. Adding the term "questionable validity" addresses the commenters' concern and improves the clarity of the final rule to meet Goal 6 of this rulemaking. The NRC retained the use of "positive" to refer to results from initial testing for drugs that indicate the presence of a prohibited drug in the specimen.

Section 26.121 Purpose.

The NRC added § 26.121 to provide an overview of the contents of the proposed subpart, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the final rule.

Section 26.123 Testing facility capabilities.

Section 26.123 amends the second sentence of former Section 2.7(l)(2) in Appendix A to Part 26 as it related to the capabilities of licensee testing facilities. The final rule retains the former 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 adds a requirement for licensee testing facilities to have the capability to perform either validity screening tests, initial validity tests, or both. The agency moved the first sentence of former Section 2.7(l)(2), which established requirements for the capabilities of HHS-certified laboratories, to Subpart G [Laboratories Certified by the Department of Health and Human Services]. The NRC deleted the last sentence of the former paragraph, which permitted the testing of breath specimens for alcohol at the collection site, because the final rule addresses alcohol testing in Subpart E [Collecting Specimens for Testing]. The NRC made these changes

to the former provision to meet Goal 6 of this rulemaking to improve organizational clarity in the final rule.

Section 26.125 Licensee testing facility personnel.

Section 26.125 amends former Section 2.6 in Appendix A to Part 26 [Licensee testing facility personnel], as follows:

Section 26.125(a) retains former Section 2.6(a) in Appendix A to Part 26. This provision 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 final rule makes minor changes in the former provision to improve consistency with amended language in the related portion of the HHS Guidelines.

Section 26.125(b) amends former Section 2.6(b) in Appendix A to Part 26. This provision required laboratory technicians and nontechnical staff to have the necessary training and skills for the tasks assigned to them. The final rule retains the former provision and adds another. The final rule requires laboratory technicians who perform urine specimen testing to demonstrate proficiency in operating the instruments and tests used at the licensee testing facility. The NRC added this proficiency requirement to ensure that technicians are capable of correctly using the instruments and tests that the licensee testing facility has selected for validity and drug testing. This change is necessary for several reasons. First, the final rule adds new requirements for licensee testing facilities to conduct validity testing, and the instruments and tests that the technicians will use are likely to differ from those previously used at licensee testing facilities. Therefore, additional training and proficiency testing is required to ensure that validity testing is conducted properly. Second, the final 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 former 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 requirement for technicians to demonstrate proficiency, then, contributes 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.

With respect to the proposed rule and in response to a public comment that proficiency documentation requirements were missing from the proposed rule in several locations, the final rule adds a requirement for licensee testing facilities to document the proficiency of its technicians. Although proposed § 26.125(c) required licensee testing facility personnel files to include documentation of training and experience and the results of tests that establish employee competency for the position he or she holds, the final rule adds a requirement for documentation of proficiency in § 26.125(b) to further clarify that this documentation is required and specifically applies to laboratory technicians who perform urine drug testing. The NRC made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.125(c) amends former Section 2.6(c) in Appendix A to Part 26. The provision establishes recordkeeping requirements for the personnel files of licensee testing facility staff. The final rule, with respect to the proposed rule, further clarifies the intent of the licensee testing facility personnel competency requirements by specifying that personnel must be proficient in conducting testing using the most recent instructions from instrument and test manufacturers. In addition, in response to comments received on the elimination of the former provision in Section 2.5(f) in Appendix A to Part 26 that required licensees and other entities to maintain color blindness testing records in files for licensee testing facility personnel, the final rule reinstates the requirement. The final rule retains the color blindness testing recordkeeping requirement because some validity screening and initial validity tests require laboratory testing

facility personnel to visually evaluate the color of the assay to determine the test result. Retaining records of color blindness testing is necessary to demonstrate licensee testing facility personnel competency.

Section 26.127 Procedures.

Section 26.127 combines, reorganizes, and amends requirements for procedures that were interspersed throughout Appendix A to Part 26, including requirements in former Sections 2.2 [General administration of testing] and 2.7 [Laboratory and testing facility analysis procedures]. These changes improve clarity in the organization of the final rule by grouping procedural requirements for licensee testing facilities in one section, consistent with Goal 6 of this rulemaking.

Section 26.127(a) makes minor editorial changes to the first sentence of former Section 2.2 in Appendix A to Part 26. The former provision required licensee testing facilities and HHS-certified laboratories to have detailed procedures for conducting testing. The final rule deletes the reference to blood samples in the former provision because donors no longer have the option to request blood testing for alcohol, as discussed with respect to § 26.83(a). For organizational clarity, the final rule moves the reference to HHS-certified laboratories to § 26.157(a) in Subpart G [Laboratories Certified by the Department of Health and Human Services]. The final rule also deletes the former reference to procedures for specimen collections in this paragraph because procedural requirements for specimen collections are addressed in Subpart E [Collecting Specimens for Testing].

Section 26.127(b) amends and combines portions of the requirements in the first sentence of former Section 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 final rule retains the portions of the former provisions that required 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. For organizational clarity, the NRC moved the former requirements related to HHS-certified laboratories to § 26.157(b) in Subpart G [Laboratories Certified by the Department of Health and Human Services]. The final rule also removes references to custody-and-control procedures for blood specimens because donors no longer have the option to request blood testing for alcohol, as discussed with respect to § 26.83(a).

Section 26.127(c) retains the portions of former Section 2.7(o)(1) in Appendix A to Part 26 that addressed the required content of procedures for licensee testing facilities and amends the former requirements. The final rule retains the portions of the former provision that required 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 final rule presents the required topics of the procedures in a list format in § 26.127(c)(1)–(c)(12) to clarify that each topic stands on its own and to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.127(c) also amends former Section 2.7(o)(1) in Appendix A to Part 26 in several ways. First, the final rule eliminates the former requirement for the procedures to be maintained in a laboratory manual as unnecessarily restrictive. The final rule permits licensee testing facilities to use other means to maintain their procedures. Second, the agency has added a requirement for the development, implementation, and maintenance of written standard operating procedures for all laboratory instruments and validity screening tests, consistent with the addition of requirements to conduct validity testing throughout the final rule. Third, the final rule moves two portions of the former provision to other subparts of the rule that address related topics to improve clarity in the organization and language of the final rule, as

follows: The agency relocated the last two sentences of former Section 2.7(o)(1) in Appendix A to Part 26, which addressed requirements for retaining copies of superceded procedures, to § 26.715(a) of Subpart N [Recordkeeping and Reporting Requirements], and the final rule moves procedural requirements for HHS-certified laboratories to § 26.157(b) in Subpart G [Laboratories Certified by the Department of Health and Human Services].

Section 26.127(d) amends former Section 2.7(o)(3)(iii) in Appendix A to Part 26. This provision required 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 final rule extends the former requirements to non-instrumented tests (such as some validity screening tests, if the licensee testing facility uses these tests), consistent with the addition of requirements to conduct validity testing throughout the final rule. The final rule also makes three organizational changes to the former provision. The final rule presents the required topics of the procedures in a list format in § 26.127(d)(1)–(d)(3) to clarify that each topic stands on its own. The NRC relocated the former requirement to maintain records of preventative maintenance to § 26.715(b)(10) in Subpart N [Recordkeeping and Reporting Requirements]. And, the NRC has moved the former requirements that applied to HHS-certified laboratories to § 26.157(d) in Subpart G [Laboratories Certified by the Department of Health and Human Services]. These changes improve clarity in the organization of the rule, consistent with Goal 6 of this rulemaking.

Section 26.127(e) reorganizes and amends former Section 2.7(o)(4) in Appendix A to Part 26. The former provision required corrective actions to be documented if systems are out of acceptable limits or errors are detected. The final rule extends the former requirement to validity screening tests if the licensee testing facility uses these tests, consistent with the addition of requirements to conduct validity testing throughout the final rule. The final rule, with

respect to the proposed rule, also adds the term “instrumented” to clarify that a licensee testing facility must develop and implement procedures for remedial actions on testing facility equipment, instruments, and tests. The NRC has moved the requirements in the former paragraph that applied to HHS-certified laboratories to § 26.157(e) in 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.

Section 26.129 has been added to group together in one section the requirements of the final rule that apply to licensee testing facilities with respect to the safeguarding of specimen identity, integrity, and security. The NRC made this organizational change because requirements that addressed these topics were dispersed throughout the former rule. Grouping them together in a single section makes them easier to locate within the final rule and meets Goal 6 of this rulemaking to improve clarity in the language and organization of the rule.

Section 26.129(a) retains the first four sentences of former Section 2.7(a)(1) in Appendix A to Part 26. The provision requires licensee testing facilities to be secure and accessible only to authorized personnel. The final rule moves the requirements in the former provision that applied to HHS-certified laboratories to § 26.159(a). The final rule moves the last sentence of the former paragraph, which established recordkeeping requirements, to § 26.715(b)(13) in Subpart N [Recordkeeping and Reporting Requirements]. The NRC made these changes for organizational clarity.

Section 26.129(b) amends former Section 2.7(b)(1) in Appendix A to Part 26. This provision established requirements for receiving specimens at the licensee testing facility and assuring their integrity and identity. For organizational clarity, the final rule moves the former requirements related to HHS-certified laboratories to § 26.159(b) in Subpart G [Laboratories Certified by the Department of Health and Human Services]. The final rule, with respect to the

proposed rule, adds § 26.129(b)(1) and (b)(2) to improve the clarity of the organization of the rule. The NRC has also added several requirements to the former provision, as follows:

In § 26.129(b), the final rule retains the requirement for licensee testing facility personnel to inspect specimens received for testing to determine whether there is any evidence of tampering with the specimens and to ensure that the custody-and-control documents are correct. With respect to the proposed rule, the final rule adds 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 will work with collection site personnel to attempt to identify the collector and obtain a memorandum for the record from the collector if possible. This requirement reduces 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 final rule, with respect to the proposed rule, adds a provision that specifies the procedures to be followed by licensee testing facility personnel to correct custody-and-control form errors that are identified after the specimen collection process has been completed and the donor has departed from the collection site. This addition is based on a comment received on the proposed rule requesting the addition of these procedures. The requirements also improve the efficiency of FFD programs by avoiding the need to conduct additional specimen collections when discrepancies can be corrected. The additional provision meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, as well as Goal 1 of this rulemaking, to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.129(b)(1) adds requirements for licensee testing facility personnel to report to management any indications of specimen tampering within 8 hours of the discovery. This provision also requires licensee or other entity management personnel to initiate an investigation to determine whether tampering has occurred. Section 26.129(b)(i) requires management to take corrective actions if tampering is confirmed. The final rule adds these requirements because some licensees did not investigate or take corrective actions in response to indications of tampering with specimens under the former rule. The appropriate corrective actions that management personnel would take depend on 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 § 26.75(b) for a subversion attempt. This provision also requires management personnel 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.

Section § 26.129(b)(1)(ii) adds a prohibition on testing of any specimen if the licensee or other entity has reason to believe that the specimen was subject to tampering or altered in a manner as to affect specimen identity and integrity. In this circumstance, the MRO will cancel testing of the specimen or any test results for the specimen, and require the licensee or other entity to retest the donor who submitted the original specimen. The final rule, with respect to the proposed rule, adds an exception for split specimen collections in response to a public comment that requested additional clarification of the proposed rule's requirements for cancelling tests. For a split specimen collection, if the tamper-evident seal remains intact on either Bottle A or Bottle B of the specimen and the bottle contains at least 15 mL of urine, the final rule requires the licensee testing facility to forward the intact specimen to the HHS-certified laboratory and prohibits any testing at the licensee testing facility. This new provision serves to

eliminate unnecessary additional specimen collections, thereby meeting Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC added § 26.129(b)(2) in the final rule, with respect to the proposed rule, to include specific instances that would require the cancellation of the testing of a donor's urine specimen. This change has been made in response to a public comment that requested the NRC to add information in the final rule to describe the actions that must be taken if the integrity of a specimen is in question. Adding this information to the final rule meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, as well as Goal 1 to improve the consistency of NRC requirements with those of other Federal agencies. The provisions are modeled on similar requirements in the DOT's drug testing program.

Although the NRC is not aware of any instances when these circumstances have arisen in Part 26 programs, the experience of other Federal agencies indicates that specimen tampering is possible. Therefore, the requirements in § 26.129(b) are necessary to ensure that donors are not subject to sanctions for positive, adulterated, substituted, or invalid test results from a specimen that may not have been theirs. These changes meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 and ensure that the individuals are afforded accurate and consistent testing. These requirements are also consistent with the requirements of other Federal agencies.

Section 26.129(c) amends former Section 2.7(b)(2) in Appendix A to Part 26. This provision established requirements for chain-of-custody procedures for specimens and aliquots at licensee testing facilities. The final rule moves the requirements in the former paragraph that were related to HHS-certified laboratories to Subpart G [Laboratories Certified by the Department of Health and Human Services] to improve organizational clarity.

The section incorporates two additional changes to the former provision at the request

of stakeholders at the public meetings discussed in Section I.D. The stakeholders requested that the NRC 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 NRC incorporated this change 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. Adding this flexibility is consistent with Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

The stakeholders also requested that the section specify the conditions under which specimens and aliquots may be discarded because the former rule did not address discarding of negative specimens. Therefore, the final rule permits licensee testing facilities to discard specimens and aliquots as soon as practical after validity screening or initial validity tests have demonstrated that the specimen is valid and initial test results for drugs and drug metabolites are negative. The clarification codifies licensee practices. This permission has no impact on donors' rights under the final rule because donors are not at risk of management actions or sanctions as a result of negative test results and, therefore, do not need the licensee testing facility to retain the specimen for additional testing for review or litigation purposes. The change has been made to meet Goal 6 of this rulemaking to improve clarity in the language of the final rule.

Section 26.129(d) updates former Section 2.7(a)(2) in Appendix A to Part 26. This provision required licensee testing facility personnel to maintain and document the chain of custody for specimens and aliquots. The final rule incorporates the simpler language of the related provision from the HHS Guidelines while retaining the intent of the former provision. The final rule relocates the requirements in the former section that were related to HHS-certified laboratories to § 26.159(d) and (e) in Subpart G [Laboratories Certified by the Department of

Health and Human Services] to improve organizational clarity.

Section 26.129(e) amends the first sentence of former Section 2.7(d) in Appendix A to Part 26 [Specimen processing]. That sentence required specimens that test as "presumptive positive" at the licensee testing facility to be shipped to the HHS-certified laboratory for further testing. The final rule replaces the term "presumptive positive" with terms to describe the specific test results, as appropriate (i.e., "positive," "questionable validity") in order to address validity testing results, consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). For organizational clarity, the agency has moved the requirements in former Section 2.7(d) in Appendix A to Part 26 that related to quality control procedures for testing at licensee testing facilities and HHS-certified laboratories to § 26.137 [Quality assurance and quality control] and § 26.167 [Quality assurance and quality control] of the final rule, respectively.

Section 26.129(f) clarifies and revises former Section 2.7(c) in Appendix A to Part 26 [Short term refrigerated storage], as it related to refrigerating urine specimens to protect them from degradation. For organizational clarity, the final rule moves the former requirements that applied to HHS-certified laboratories to § 26.159(h) in Subpart G [Laboratories Certified by the Department of Health and Human Services]. The final rule restates portions of the former provision and adds a performance standard regarding "appropriate and prudent actions" to minimize specimen degradation. For the reasons discussed with respect to § 26.117(j), the final rule no longer requires all specimens to be refrigerated within 6 hours after collection, but adds a requirement that any specimen that has not been tested within 24 hours of receipt at the licensee testing facility must be refrigerated. The final rule continues 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 a positive test result from initial drug testing at the licensee testing facility. The final rule also adds a requirement for

refrigerating any specimen (and the associated Bottle B specimen if a split specimen collection is performed) that yields a questionable validity test result from validity screening or initial validity testing. Refrigerating these specimens is necessary because some adulterants have been shown to interfere with drug test results more rapidly if the specimen remains at room temperature.

The final rule also updates the terminology used in the former paragraph to be consistent with the new terminology adopted throughout the final rule for referring to split specimens. Therefore, in the final rule, the licensee testing facility continues 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 rule also requires the licensee testing facility to refrigerate any specimen that yields a positive test result or a questionable validity test result. This includes the specimen in Bottle B associated with any aliquot that yields a positive or questionable validity test result at the licensee testing facility. The NRC made these changes in the terminology of the paragraph to improve clarity in the language of the final rule.

The final rule separates former Section 2.4(i) in Appendix A to Part 26 [Transportation to laboratory or testing facility] into two paragraphs, § 26.129(g) and (h), for organizational clarity and amends the former provision for the reasons previously discussed with respect to § 26.117(i) and (k). Section 26.129(g) and (h), which repeats the requirements for packaging and shipping specimens contained in § 26.117(i) and (k) of Subpart E [Collecting specimens for testing], applies these requirements to packaging and shipping specimens from licensee testing facilities to HHS-certified laboratories. The basis for these requirements is discussed with respect to § 26.117(i) and (k).

Section 26.131 Cutoff levels for validity screening and initial validity tests.

The NRC has added § 26.131 to establish cutoff levels for validity screening and initial validity tests that are conducted at licensee testing facilities. The procedures, substances, and cutoff levels for initial validity testing in this section incorporate related requirements from the HHS Guidelines (69 FR 19643; April 13, 2004). The validity screening test requirements have been adapted, in large part, from the HHS proposed revision to the Guidelines that was also published in the *Federal Register*on April 13, 2004 (69 FR 19673).

In contrast to the requirements for initial validity testing in the HHS Guidelines, the final rule does not permit licensee testing facilities to evaluate the specific gravity of any specimens. To determine if a specimen is dilute or substituted, specific gravity testing is required. If the creatinine concentration of a specimen is less than 20 mg/dL, the final rule requires the licensee testing facility to forward the specimen to the HHS-certified laboratory to complete the testing, where the specimen's specific gravity will be measured. The final rule differs 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 final rule requires licensee testing facilities to transfer all specimens with creatinine concentrations less than 20 mg/dL to an HHS-certified laboratory to complete the initial testing process and does not include cutoff levels for specific gravity or quality control requirements for measuring specific gravity.

Section 26.131(a) has been 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 a specimen at an HHS-certified laboratory when initial drug testing at the licensee testing facility yields a positive test result, the final rule also requires licensee testing

facilities to forward specimens that yield a questionable validity screening or initial validity test result 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 required 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 ensure that donors are afforded accurate and consistent testing under this part, 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 on more complex instrumented testing technologies. The final rule permits licensee testing facilities to perform validity screening tests before performing initial validity tests but does not require them to do so because validity screening tests are unnecessary if the licensee testing facility performs initial validity testing. Licensees and other entities may choose to conduct validity screening tests, followed by initial validity testing of any specimens that are identified to be of questionable validity as a result of validity screening, potentially to reduce the number of donor specimens that must be forwarded to the HHS-certified laboratory. In addition, the rule permits licensee testing facilities to choose whether to conduct validity screening tests or initial validity testing for each type of validity testing that is required under the rule. For example, a licensee or other entity may choose to use dipsticks (a validity screening test) to evaluate a specimen's creatinine concentration and only a pH meter (a method for conducting initial validity testing) without first performing a validity screening test for pH to evaluate the specimen's pH. The NRC is permitting flexibility in the means licensee testing facilities use to conduct specimen validity testing to meet Goal 3 of this rulemaking to enhance the efficiency and effectiveness of FFD

programs.

Section 26.131(b) requires licensee testing facilities to test each urine specimen for creatinine concentration, pH, and the presence of one or more oxidizing adulterants, such as nitrite or bleach. Abnormal creatinine concentrations, abnormal pH values, or the possible presence of an oxidizing adulterant indicate that a donor may have altered the specimen (e.g., adulterated the specimen or substituted another substance in place of the donor's urine) in an attempt to subvert the testing process. The final rule permits licensees and other entities to choose the oxidizing adulterant(s) for which testing will be conducted. The requirements in this paragraph are consistent with the related requirements in the HHS Guidelines.

Because validity testing is complex and the methods for testing are relatively new, the second sentence of § 26.131(b) prohibits an FFD program from establishing more stringent cutoff levels for validity screening and initial validity testing than the cutoff levels established in this provision. This prohibition is necessary to decrease the risk of obtaining false adulterated, substituted, or invalid test results and ensures that donors are not subject to sanctions on the basis of inaccurate test results.

Section 26.131(b)(1)–(b)(8) specifies the criteria for determining whether the licensee testing facility must forward a specimen to an HHS-certified laboratory for further validity testing. These criteria are incorporated from the HHS Guidelines. With respect to the proposed rule, the agency modified the requirements in the final rule in response to public comments received on the proposed specimen pH and nitrite levels. Specifically, the commenters identified that the proposed rule did not include pH and nitrite levels that would permit the licensee testing facility to detect a specimen that meets the criteria for an invalid test result in the HHS Guidelines. Therefore, § 26.131(b)(2) in the final rule establishes a pH level of less than 4.5, rather than a pH level of less than 3.0 in the proposed rule, as one criterion for determining that a specimen requires additional validity testing. The NRC also revised the

nitrite concentration from equal to or greater than 500 micrograms (mcg) per mL in proposed § 26.131(b)(3) to equal to or greater than 200 mcg/mL in the final rule. These changes to the pH and nitrite criteria in the final rule are consistent with the current HHS Guidelines and meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. By ensuring detection of specimens that may be invalid, these changes also meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.133 Cutoff levels for drugs and drug metabolites.

Section 26.133 replaces former Section 2.7(e)(1) in Appendix A to Part 26. That section established cutoff levels for initial testing for drugs and drug metabolites. Section 26.133 replaces and amends some cutoff levels for initial tests for drugs and drug metabolites in former Section 2.7(e)(1) in Appendix A to Part 26 to be consistent with the HHS cutoff levels for the same substances.

The NRC has decreased the initial test cutoff level for marijuana metabolites 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 change strengthens the effectiveness of FFD programs by increasing the likelihood of detecting marijuana use.

The final rule increases the initial test cutoff level for opiate metabolites from 300 ng/mL in the former rule to 2,000 ng/mL. The change in the cutoff level for opiate metabolites substantially reduces the number of positive opiate test results that are reported to MROs by HHS-certified laboratories that MROs ultimately verify as negative.

The final rule retains the permission in the former rule for licensees and other entities to establish more stringent cutoff levels for initial drug tests, subject to the requirements specified

in § 26.31(d)(3)(iii), for the reasons discussed with respect to that paragraph.

The final rule eliminates the former requirement for licensees and other entities to report drug test results for both the cutoff levels in the former rule and any more stringent cutoff levels they applied. The NRC in the former rule required FFD programs to report test results for the cutoff levels specified in this part, when the licensee was applying more stringent cutoff levels, because it provided means for the NRC to monitor licensees' implementation of the permission to use more stringent cutoff levels. The final rule eliminates this requirement because § 26.31(d)(3)(iii)(C) requires 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 is no longer needed to ensure licensee testing facility performance in this area. Eliminating this requirement meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.135 Split specimens.

The NRC has added § 26.135 to reorganize and amend the requirements contained in former Section 2.7(j) in Appendix A to Part 26 that related to licensee testing facility handling of split specimens. The requirements in this section apply only to FFD programs that follow split specimen collection procedures. The NRC has divided the former provision into separate paragraphs in this section to indicate that each requirement stands on its own. This change has been made to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the final rule.

Section 26.135(a) amends the second, third, and fourth sentences of former Section 2.7(j) in Appendix A to Part 26. The final rule revises the terminology used in these sentences (e.g., "Bottle A" rather than "primary specimen," "Bottle B" rather than "split specimen," "positive or of questionable validity " rather than "presumptive positive") to be

consistent with terminology used in other parts of the regulation without amending the meaning of the sentences. The final rule deletes the requirement in the third sentence of former Section 2.7(j) to seal the split specimen prior to placing it in secure storage because Bottles A and B have already been sealed at the collection site, as required under § 26.113(b)(3). The final rule adds a requirement to forward the Bottle A specimen to an HHS-certified laboratory if the licensee testing facility obtains a questionable validity test result. This requirement is consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). With respect to the proposed rule, the final rule adds a requirement that Bottle B specimens must remain in secure storage under the requirements in § 26.159(i) if the licensee testing facility retains Bottle B specimens rather than sending the specimens to the HHS-certified laboratory with Bottle A specimens.

Section 26.135(b) amends the requirements in former Section 2.7(j) in Appendix A to Part 26 related to donor requests for testing of the specimen in Bottle B. The final rule adds adulterated or substituted 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 final rule, as discussed with respect to § 26.31(d)(3)(i). The final rule, with respect to the proposed rule, imposes a requirement on the MRO to ensure that Bottle B is forwarded to a second HHS-certified laboratory that did not test the specimen in Bottle A, at the request of the donor, and to follow the procedures specified in § 26.165(b). In addition, the NRC eliminated the procedures for donor requests for testing the specimen in Bottle B that were included in this provision in the proposed rule because they were incomplete and partially redundant with the related provision in § 26.165(b). The NRC made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule eliminates the requirement in the fourth sentence of former Section 2.7(j) in Appendix A to Part 26 that required the licensee testing facility or HHS-certified laboratory to

forward the split specimen to another HHS-certified laboratory for testing on the same day of the donor request. The final rule, with respect to the proposed rule, references the provisions in § 26.165(b) pertaining to the time period (1 business day) within which licensee testing facilities must forward a specimen to a second HHS-certified laboratory following the donor request. This change responds to stakeholder feedback provided during the public meetings discussed in Section IV.D. The stakeholders reported that implementing the former same-day requirement was often 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 on the nature of the non-negative test result. The final rule alleviates some of these logistical difficulties (e.g., logistical problems associated with weekends and holidays) while continuing to provide the donor with timely test results. Therefore, the NRC made this change to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.135(c) amends former Section 2.7(c) in Appendix A to Part 26 that applied to storing specimens at licensee testing facilities. The NRC has amended some of the terminology used in the former provision for consistency with the terminology changes made throughout the rule. For example, the provision replaces the term “split specimen” with the term “Bottle B.” In addition, the final rule imposes the requirements for long-term frozen storage of split specimens in former Section 2.7(h) in Appendix A to Part 26 on licensees and other entities who choose to retain Bottle B of a split specimen at the licensee testing facility rather than forwarding it with Bottle A to the HHS-certified laboratory when additional testing at the HHS-certified laboratory is required. The final rule requires licensees and other entities to ensure that Bottle B of any specimen that the MRO has confirmed to be positive, adulterated, substituted, or invalid is retained in long-term frozen storage for at least 1 year. The final rule,

with respect to the proposed rule, includes a requirement that licensee testing facilities who retain Bottle B specimens must ensure that proper specimen storage conditions (i.e., frozen storage) are maintained during extended power outages. This change is based on comments received on the proposed rule noting the oversight. The final rule is consistent with former Section 2.7(c) in Appendix A to Part 26, which required licensee testing facilities to have emergency power equipment available in case of a prolonged power failure. The final rule extends the former requirement to apply to Bottle B of any specimen that has yielded adulterated, substituted, or invalid validity test results, consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). The final rule moves the portions of former Section 2.7(h) in Appendix A to Part 26 that applied to HHS-certified laboratories to § 26.159(i) in subpart G [Laboratories Certified by the Department of Health and Human Services] to improve the organizational clarity of the final rule.

Section 26.137 Quality assurance and quality control.

The NRC has added § 26.137 to amend former Section 2.8 in Appendix A to Part 26 [Quality assurance and quality control] . This section adds 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 discussed with respect to each paragraph. The final rule incorporates the related requirements from the HHS Guidelines to meet, in part, Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. The NRC has relocated the portions of former Section 2.8 in Appendix A to Part 26 that established requirements for HHS-certified laboratories to § 26.167 in Subpart G [Laboratories Certified by the Department of Health and Human Services] of the final rule for organizational clarity. The agency has made many

changes in this section with respect to the proposed rule in response to detailed technical comments the NRC received on the proposed rule. The performance testing and quality control requirements in the final rule are consistent, in large part, with those required for initial testing at the HHS-certified laboratories.

Section § 26.137(a) [Quality assurance program] amends former Section 2.8(a) in Appendix A to Part 26, which required licensee testing facilities and HHS-certified laboratories to have a quality assurance program for all aspects of the testing process. The NRC moved the former requirements related to HHS-certified laboratories to § 26.167(a) in Subpart G [Laboratories Certified by the Department of Health and Human Services] to improve organizational clarity. The final rule extends the former requirements for licensee testing facilities to have a quality assurance program and procedures for drug testing 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).

Section 26.137(b) [Performance testing and quality control requirements for validity screening tests] establishes new requirements for performance testing and quality control of validity screening testing at the licensee testing facility. This section permits licensee testing facilities to use validity screening tests to determine whether a specimen is valid or must be subject to further validity testing. However, any specific validity screening test that a licensee testing facility chooses to use (e.g., a validity screening test for creatinine concentration, a validity screening test for pH, a validity screening test for oxidizing adulterants) must meet the stringent performance testing requirements in this section. The requirements in this section are based on requirements that were proposed by HHS in a Notice of Proposed Revisions to the Mandatory Guidelines dated April 13, 2004 (69 FR 19673). However, in response to detailed public comments on the proposed rule and further technical analyses, the NRC has revised several of the proposed HHS requirements that were incorporated in this section in the

proposed rule, as discussed with respect to each provision the NRC has changed.

Section 26.137(b)(1) permits licensee testing facilities to use validity screening tests to determine whether a specimen is valid or must be subject to further validity testing. However, under § 26.137(b)(1)(i) and (ii), the NRC requires licensee testing facilities to use only validity screening tests that either have been 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 § 26.137(b)(1)(ii) for the reasons discussed with respect to that provision. With respect to the proposed rule, § 26.137(b)(1) in the final rule includes a new provision to address an unintentional omission in the proposed rule. Specifically, the NRC has added a requirement that licensee testing facilities must use an HHS-certified laboratory that has the capabilities to confirm the presence of any adulterant for which the licensee testing facility conducts validity screening tests. The inclusion of this provision is necessary because, as proposed, a licensee testing facility could have used a validity screening test that identified an adulterant that the HHS-certified laboratory could not identify because the laboratory did not also test for the adulterant in their validity testing panel. If this was the case, a specimen with a questionable validity result from a licensee testing facility would be tested by the HHS-certified laboratory and the specimen would receive a negative or invalid validity test result, creating conflicting results. The final rule resolves this inconsistency.

In addition, the final rule eliminates the term, “non-instrumented devices,” that was used in proposed § 26.137(b)(1). By eliminating the specific reference to non-instrumented tests and by revising the definition of “validity screening test” in § 26.5 [Definitions], the NRC is permitting licensee testing facilities to use instrumented tests, in addition to non-instrumented tests, to perform validity screening testing. The NRC made this change in response to a public comment. The commenter suggested that the proposed requirement that limited licensee

testing facilities to using only non-instrumented devices to perform validity screening tests was unduly restrictive. Specifically, the commenter stated that instrumented tests could successfully meet the performance testing requirements (e.g., pH testing) for some validity screening tests described in proposed § 26.137(b)(1). The inclusion of instrumented tests for validity screening testing meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

In § 26.137(b)(1)(i) of the final rule, the NRC permits licensee testing facilities to use validity screening tests that are identified, by lot number, on the SAMHSA list of point-of-collection tests approved for use in the Federal Workplace Drug Testing Program, as published in the Federal Register. The NRC is aware that SAMHSA has yet to publish a list of approved point-of-collection tests but added this permission so that licensee testing facilities may rely on that list when it is available. With respect to the proposed rule, the final rule has removed the requirement that validity screening tests must be cleared by the FDA in response to a public comment. The NRC eliminated the proposed requirement because, as the commenter pointed out, the FDA is not responsible for clearing specimen validity point-of-collection tests. The final rule also clarifies the proposed provision by adding the requirement that licensee testing facilities may only use validity screening tests from “lots” (i.e., batches or groups of tests that are manufactured from the same original materials) that are identified on the SAMHSA list when it is available. The NRC added this clarification because SAMHSA approval will apply to all validity screening tests from the same lot but may not apply to other lots of the test that do not meet SAMHSA’s criteria for approval.

Because SAMHSA has yet to publish a list of approved validity screening tests, the NRC has added § 26.137(b)(1)(ii) to permit licensee testing facilities to use validity screening tests that meet the stringent performance testing requirements established in this section. Adding these requirements to the final rule permits licensee testing facilities to conduct the required

performance testing and begin using any validity screening tests that meet the criteria before SAMHSA's list is published. The NRC is aware that the performance testing requirements in § 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 positive initial drug test result for marijuana or cocaine from a specimen that yields negative test results from validity screening (see proposed §26.75(i)), it is critical that any validity screening tests used in Part 26 programs provide accurate results. The proposed performance testing requirements are necessary to protect donors from inaccurate results and ensure that specimens of questionable validity are detected.

The final rule eliminates the proposed provision in § 26.137(b)(1)(ii)(A) that required a licensee testing facility or HHS-certified laboratory to conduct performance testing of 100 validity screening devices from all currently available manufactured lots of the device to ensure that the devices met the performance testing criteria in proposed § 26.137(b)(1)(ii)(C) before the licensee testing facility began using the validity screening test. The NRC eliminated proposed § 26.137(b)(1)(ii)(A) to address public comments received suggesting that licensee testing facilities and HHS-certified laboratories may not have the experience or expertise to conduct performance testing of validity screening devices. The commenters suggested that the NRC should instead consider requiring the manufacturer of the validity screening tests to perform and document validation studies of the validity screening tests as well as conduct tests of performance testing samples that licensee testing facilities submit to the manufacturer. The NRC agrees with the commenters and has revised the proposed rule to require manufacturers to perform and document validation studies in § 26.137(b)(1)(ii)(D) of the final rule. The final rule also requires licensees and others entities that intend to use validity screening tests to submit performance testing samples to the validity screening test manufacturer in § 26.137(b)(1)(ii)(E) of the final rule. This change ensures that the evaluation of a validity

screening test is conducted by an individual(s) endorsed by the manufacturer. If an individual with limited training were used to conduct the tests, the manufacturer may have a reason to question the test results obtained by the licensee testing facility or the HHS-certified laboratory. The NRC believes that the validity screening test manufacturer is best qualified to demonstrate the effectiveness of each test because the manufacturer is the entity with the greatest knowledge of correct testing procedures.

Another public comment received on proposed § 26.137(b)(1)(ii)(A) stated that the requirement to test 100 validity screening devices was overly burdensome. The NRC agrees with the commenter, has revised the requirement, and relocated the amended provision to § 26.137(b)(1)(ii)(E). The new § 26.137(b)(1)(ii)(E) requires a licensee or other entity to submit three consecutive sets (at least 6 samples in each set) of performance testing samples to the validity screening test manufacturer for performance testing before the licensee testing facility begins using a validity screening to test donor specimens. Therefore, the final rule requires the licensee or other entity to submit a minium of 18 samples for each validity screening test to be used by a licensee or other entity. If a licensee or other entity chooses to use validity screening tests to conduct all of the validity testing required by this subpart (e.g., creatinine, pH, and oxidizing adulterants), the total minimum number of performance test samples that a licensee testing facility must submit to meet the minimum performance testing requirements in the final rule is 72 samples (18 samples for a creatinine test divided into three sets, 18 samples for pH testing at levels equal to or less than 4.5 divided into three sets, 18 samples for pH testing at levels equal to or greater than 9 divided into three sets, and 18 samples for an oxidant test divided into three sets). If a licensee or other entity chooses to use a validity screening test for only one of the types of validity testing required in this subpart, the total number of performance test samples that the licensee testing facility must submit is less. For example, if a licensee or other entity chooses to use a validity screening test only for determining creatinine

concentration, the total number of performance samples that the licensee testing facility must submit for testing is 18 samples divided into three sets. The NRC believes that the revised performance testing sample requirements reduce the burden on licensees and other entities imposed by these performance testing requirements while ensuring that the validity screening tests provide accurate and consistent test results.

The agency has also relocated and revised the requirements in proposed § 26.137(b)(1)(ii)(B) and (b)(1)(ii)(C). These proposed provisions established requirements for the formulation of performance testing samples and criteria for licensees and other entities to apply when evaluating performance testing results, respectively. The final rule combines these requirements in § 26.137(b)(1)(ii)(E) and presents them in the rule in the sequence in which licensees and other entities would implement them for organizational clarity. The NRC has also made other changes to the provisions in proposed § 26.137(b)(1)(ii) to address a public comment that stated that the performance testing standards in the proposed rule were unduly prescriptive and should instead be performance based. The NRC agrees with the commenter and has further revised the performance testing provisions in proposed § 26.137(b) as is subsequently discussed with respect to each provision in the final rule.

Section 26.137(b)(1)(ii)(A) of the final rule specifies that a validity screening test that a licensee testing facility intends to use to conduct creatinine testing must be able to detect whether a specimen's creatinine concentration is less than 20 mg/dL. This provision replaces the portions of proposed § 26.137(b)(1)(ii)(B) and (b)(4) that established the required creatinine measurement capabilities of validity screening devices. The NRC revised the provision in response to a public comment received on proposed § 26.137(b)(4) that stated that tests currently available that could be used for validity screening testing for creatinine cannot distinguish creatinine concentrations in the proposed ranges of 5-20 and 1-5 mg/dL. The commenter noted that current validity screening tests, at best, can detect creatinine

concentration at a cutoff of 20 mg/dL. Because the rule does not require licensee testing facilities to determine whether a specimen meets the criteria for substitution or dilution, which depend on the results of specific gravity testing in addition to lower creatinine concentrations, the NRC agrees with the commenter that the proposed creatinine testing to lower concentrations is unnecessary. A validity screening test that can detect creatinine concentration at a cutoff of 20 mg/dL is adequate for a licensee testing facility to determine that a specimen is of questionable validity and requires further testing at an HHS-certified laboratory. This revision avoids imposing an unnecessary burden on licensee testing facilities while ensuring that the validity screening test will support the creatinine concentration cutoff at 20 mg/dL established in § 26.131(b)(1).

Section 26.137(b)(1)(ii)(B) of the final rule specifies that a validity screening test that a licensee testing facility intends to use to conduct pH testing must be able to identify specimens with pH of less than 4.5 and pH equal to or greater than 9. This provision replaces the portions of proposed § 26.137(b)(1)(ii)(B) and (b)(4) that established the required pH measurement capabilities of validity screening devices. Proposed § 26.137(b)(1)(ii)(B) and (b)(4) would have required pH validity screening tests to be capable of detecting pH in the ranges of 1-3 and 10-12. However, the NRC received two comments noting that the proposed pH ranges would not permit the licensee testing facility to detect a specimen that meets the criteria for an invalid test result in the HHS Guidelines (i.e., pH less than 4.5 or equal or greater than 9). Therefore, this change addresses the issue raised by the commenter and ensures that the validity screening test will support the pH cutoffs established in § 26.131(b)(2) as revised in the final rule.

Section 26.137(b)(1)(ii)(C) of the final rule specifies the required performance capabilities for a validity screening test that a licensee testing facility intends to use to conduct testing for oxidizing adulterants. This provision replaces the portions of proposed § 26.137(b)(1)(ii)(B) and (b)(4) that established the required oxidizing adulterant measurement

capabilities of validity screening devices. Proposed § 26.137(b)(1)(ii)(B) and (b)(4) would have required oxidizing adulterant validity screening tests to be capable of detecting nitrite in the ranges of 250 mcg/mL to 400 mcg/mL and from 650 mcg/mL to 800 mcg/mL. However, one commenter on the proposed rule noted that the proposed nitrite concentrations for performance testing samples ranging from 250 mcg/mL to 400 mcg/mL and from 650 mcg/mL to 800 mcg/mL would not identify specimens that meet the invalid specimen testing criteria in the HHS Guidelines (i.e., nitrite concentration equal to or greater than 200 mcg/mL). The NRC agrees with the commenter and has revised the oxidant measurement requirements for validity screening tests to detect nitrite concentration at a cutoff of 200 mcg/mL in § 26.137(b)(1)(ii)(C) of the final rule. For completeness, the final rule also includes performance testing criteria for additional oxidant tests (i.e., chromium, halogen) that a licensee testing facility could perform to meet the requirements for testing for oxidizing adulterants in § 26.131(b). Therefore, these changes improve the clarity of the performance testing requirements in this section and the consistency of the final rule with the HHS Guidelines.

At the suggestion of a commenter, the NRC has added § 26.137(b)(1)(ii)(D) to the final rule. This provision requires the manufacturer of a validity screening test to conduct and document validation studies demonstrating the performance characteristics of the validity screening test around the cutoff levels established in this subpart. The commenter suggested that the majority of the burden of demonstrating the performance capabilities of validity screening tests should rest with the manufacturer rather than with licensees and other entities or HHS-certified laboratories, as required by several provisions of the proposed rule. The NRC agrees with the commenter and believes that the manufacturer of each validity screening test is the most appropriate entity to demonstrate the performance characteristics of the validity screening tests before a licensee or other entity begins using a test in an FFD program. The NRC believes it is necessary to establish requirements similar to those that exist for other types

of testing performed by licensee testing facilities and HHS-certified laboratories. Both the former and final rules require licensee testing facilities and HHS-certified laboratories to validate their analytical methods before conducting drug testing of donor specimens. The requirement for manufacturers to validate their validity screening tests before providing them to licensee testing facilities is essentially parallel to these requirements for licensee testing facilities and HHS-certified laboratories. The NRC believes the validation requirement is necessary to ensure that the manufacturer has verified the performance characteristics of the validity screening test before shipment to suppliers and use by licensee testing facilities.

As discussed with respect to proposed § 26.137(b)(1)(ii)(A), the NRC has revised the performance testing requirements in proposed § 26.137(b)(1)(ii)(A)–(b)(1)(ii)(C). In addition to the changes to performance testing requirements previously discussed, the final rule revises the portion of proposed § 26.137(b)(1)(ii)(C) that established the percentage of total performance test samples that validity screening tests must correctly identify when licensees and other entities submit performance testing samples to the manufacturer. In § 26.137(b)(1)(ii)(E), the NRC has increased this required percentage from 80 percent in the proposed rule to 90 percent in the final rule. The more rigorous criterion for validity screening tests increases consistency among the rule's criteria for licensee testing facility drug testing performance and criteria in the HHS Guidelines for HHS-certified laboratory drug and validity testing performance. The NRC has made this revision in the final rule to ensure that validity screening tests perform accurately and reliably and that each FFD program effectively evaluates the validity of urine specimens.

Section 26.137(b)(1)(iii) revises proposed § 26.137(b)(1)(iii) to further reduce the performance testing burden on licensees and other entities who use validity screening tests. The proposed rule would have required licensees and other entities to ensure the continued effectiveness of any validity screening tests it is using, after they have been placed in service,

by conducting or requesting the HHS-certified laboratory to conduct performance testing of 50 devices on a nominal annual frequency. Consistent with other changes to the performance testing requirements in § 26.137(b), the final rule requires the validity screening tests' manufacturers to conduct this followup performance testing rather than licensee testing facilities or HHS-certified laboratories as proposed. In addition, the final rule eliminates the specific requirement for testing of 50 devices annually and replaces it with a performance-based standard in response to a public comment suggesting that the specificity in the proposed provision was unnecessarily burdensome. The final rule does not specify the number of performance testing samples to be tested by the manufacturer using validity screening tests from the lot in use by the licensee testing facility. The final rule instead requires the manufacturer to test performance testing samples that are formulated around the cutoff levels for validity testing in this subpart. The NRC believes this standard is adequate to determine whether validity screening tests in each lot are continuing to provide accurate and consistent test results and avoids imposing unnecessarily restrictive requirements.

The NRC has eliminated proposed § 26.137(b)(1)(iv) from the final rule. That provision required licensees and other entities to ensure that the manufacturer of a validity screening test that is used by the licensee testing facility informs the licensee or other entity of any changes to the device that may require additional performance and to conduct additional performance testing if recommended by the MRO or HHS-certified laboratory. This provision is no longer necessary because the revised performance testing requirements in the final rule are focused on each lot of validity screening tests the licensee testing facility intends to use. Because manufacturers cannot make changes to a validity screening test after a lot of the tests has been produced, information about changes to the tests in that lot and additional performance testing are not required.

Section 26.137(b)(2) establishes quality control requirements that licensee testing

facility personnel must implement at the beginning of any 8-hour period when validity screening tests will be performed and while conducting validity screening testing. With respect to the proposed rule, the NRC has revised the quality control requirements that were in § 26.137(b)(2) in the proposed rule and relocated them to § 26.137(b)(2)(i). The agency made this change because the final rule adds a new § 26.137(b)(2)(ii) and it is necessary to group the related requirements together for organizational clarity in the final rule.

In response to a public comment, the agency has revised § 26.137(b)(2) in the final rule to require that the licensee testing facility personnel who will be or are performing validity screening testing must implement the quality control requirements in this section. The commenter reasoned that because some validity screening tests have visually read endpoints, the test result must be interpreted by the tester. Therefore, it is necessary to verify that each tester is able to interpret the quality control samples correctly before conducting tests on donor specimens and during the testing process. The NRC agrees with this comment and made the appropriate change in the final rule.

Section § 26.137(b)(2)(i) revises portions of proposed § 26.137(b)(2) and requires that the quality control samples to be tested before beginning to test donor specimens in any 8-hour period must consist of one sample that is certified as negative and one that is formulated to appropriately challenge each type of validity screening test to be conducted (e.g., certified to contain an oxidizing adulterant, to have creatinine below 20 ng/mL). For example, the final rule requires that if a licensee testing facility is using a validity screening test to determine the nitrite concentration of a specimen, licensee testing facility personnel must use a certified quality control sample containing nitrite. This requirement is necessary to verify that the validity screening tests to be used are functioning properly and that licensee testing facility personnel are able to conduct the tests appropriately, as discussed with respect to § 26.137(b)(2). The final rule replaces the term “non-negative” in the proposed rule, which was used to describe the

quality control samples that licensees and other entities must use, with a requirement that the quality control samples must be formulated to challenge each validity screening test around the cutoffs for initial validity testing specified in this subpart. The NRC made this change to improve the clarity in the language of the rule, as discussed with respect to § 26.5 [Definitions].

The final rule, with respect to the proposed rule, adds a provision to require validity screening tests to be challenged by licensee testing facility personnel after screening every 10 donor specimens in § 26.137(b)(2)(ii). Specifically, this provision requires the licensee testing facility to test at least 1 quality control sample after testing every 10 donor specimens during an 8-hour testing period and requires the quality control sample to be formulated to challenge the validity screening test(s) in use around the cutoffs specified in Subpart F. The NRC has added this provision to enhance the consistency of quality control procedures for conducting validity screening testing with quality control procedures for conducting initial validity and drug testing at licensee testing facilities. As discussed with respect to § 26.137(d) and (e), the NRC requires licensee testing facilities to test calibrators, controls, and blind quality control samples during each analytical run of initial validity and drug testing conducted at the licensee testing facility (See § 26.5 for a discussion of the term, “analytical run”) to monitor the accuracy of testing. However, because it may not be possible to conduct validity screening tests in batches (i.e., the tester may have to insert a dipstick into an aliquot of each donor’s specimen manually), it is impractical to impose similar requirements for calibrators, controls and blind quality control testing each time a single validity screening test is performed. Therefore, the NRC added this provision to ensure, without imposing unrealistic requirements, that validity screening tests continue to perform reliably during any 8-hour period in which the validity screening tests are used and to increase consistency among quality control requirements for validity screening and initial validity and drug testing in this section.

The NRC has moved the requirements in proposed § 26.137(b)(2) that addressed the

steps that licensee testing facilities must take if a validity screening tests fails to perform correctly when testing quality control samples. For organizational clarity, the NRC relocated the proposed provisions to § 26.137(f) in the final rule because § 26.137(f) establishes requirements related to the topic of the proposed provisions, errors in testing.

Section 26.137(b)(3) requires licensee testing facility personnel to submit 1 out of every 10 donor specimens that yield negative results using validity screening tests to an HHS-certified laboratory. This requirement is necessary to detect false negative test results from validity screening tests. A false negative test result in this instance is a result from a validity screening test indicating that the specimen is valid when, in fact, validity testing at the HHS-certified laboratory identifies the specimen as adulterated, substituted, or invalid. Assessing the validity screening test's rate of false negative test results is necessary because false negative results from a validity screening test 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, an individual who has demonstrated that he or she is not trustworthy and reliable would be permitted to perform duties under this part and may pose a risk to public health and safety and the common defense and security.

With respect to the proposed rule, the NRC has moved the requirements in proposed § 26.137(b)(3) that addressed the steps that licensee testing facilities must take if the HHS-certified laboratory's results indicate that the validity screening test provided a false negative result. For organizational clarity, the NRC relocated the proposed provisions to § 26.137(f) in the final rule because § 26.137(f) establishes requirements related to the topic of the proposed provisions, errors in testing.

The NRC notifications required in § 26.137(b)(2)and (b)(3) are necessary because false negative results from a validity screening test indicate the laboratory testing process may not be

successfully detecting donor attempts to subvert the testing process through specimen adulteration or substitution. For example, if an individual had adulterated his or her specimen and it was not detected because of a faulty test, the licensee or other entity would have no reason to terminate the individual's authorization. As a result, an individual who has demonstrated that he or she is not trustworthy and reliable would be permitted to perform duties under this part and may pose a risk to public health and safety and the common defense and security. The NRC will use the information to ensure that HHS is notified of the test failure as well as inform other licensees and entities who may also be using the test of the false negative results to prevent additional testing errors. Therefore, the notifications are 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 test are detected and corrected as soon as possible.

In response to public comments, the NRC has eliminated proposed § 26.137(b)(4) that required validity screening tests to be capable of measuring a specimen's creatinine concentration to 1 decimal place. Specificity below 20 mg/dL is unnecessary because NRC is not requiring licensee testing facilities to conduct the tests for specific gravity that are necessary for reporting substituted, dilute, or invalid validity test results, as discussed with respect to § 26.137(b)(1)(ii)(A). This change reflects the current capabilities of validity screening tests and supports the intent of the NRC that licensee testing facilities need only be able to identify whether a specimen has a creatinine concentration of less than 20 mg/dL and therefore requires additional testing at an HHS-certified laboratory.

The NRC has added a new § 26.137(b)(4) in the final rule to establish requirements for storing validity screening tests and requires licensee testing facilities to maintain the tests consistent with the manufacturer's storage specifications. Storing the tests as required by the manufacturer's instructions is necessary to ensure that the tests continue to function optimally.

This requirement is consistent with the quality control requirements for ASDs in § 26.91(d) and meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has deleted proposed § 26.137(b)(5) and (b)(6) from the final rule and replaced these provisions with the performance testing requirements in § 26.137(b)(1)(ii) for the reasons discussed with respect to that section.

The NRC added § 26.137(c) [Validity screening test results] to specify the actions that the licensee testing facility must take if a donor's specimen yields questionable results from validity screening testing. If a specimen has a questionable validity screening test result, the final rule requires instrumented initial validity testing either at the licensee testing facility or the HHS-certified laboratory. This provision is consistent with the rule's requirements for transferring to the HHS-certified laboratory specimens with initial positive drug test results from testing at a licensee testing facility. Further testing of a specimen of questionable validity is 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 final rule. The final rule, with respect to the proposed rule, eliminates the term "non-negative" from the heading of the provision for the reasons discussed with respect to § 26.5 [Definitions] related to the elimination of this term throughout the final rule.

The agency added § 26.137(d) [Quality control requirements for performing initial validity tests] to specify the required methods for performing initial validity tests at a licensee testing facility that are necessary to ensure that initial validity testing at the licensee testing facility provides accurate results. The requirements in this paragraph incorporate the related requirements in the HHS Guidelines as revised on April 13, 2004 (69 FR 19644). The paragraph has been added to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.137(d)(1) requires licensee testing facilities to measure creatinine concentration to 1 decimal place and establishes requirements for the controls to be used in initial tests for creatinine concentration.

Section 26.137(d)(2) establishes quality control requirements for performing initial pH tests. Sections 26.137(d)(2)(i)–(d)(2)(v) specify the required calibrators and controls for initial pH testing, based on the type of testing instrument used and whether a pH validity screening test has been performed.

Section 26.137(d)(3) establishes quality control requirements for performing initial tests for oxidizing adulterants, including nitrite, and § 26.137(d)(4) establishes quality control requirements for performing initial tests for "other" adulterants at the licensee testing facility.

Section 26.137(d)(5) requires that one of the quality control samples included in each analytical run must appear to be a donor specimen to laboratory analysts. The final rule retains the related requirement in the last paragraph of Section 2.8(c)(3) in Appendix A to Part 26 and amends the provision to be consistent with the same requirement in the HHS Guidelines. With respect to the proposed rule, the NRC relocated this requirement from proposed § 26.137(e)(7) to § 26.137(d)(5) in the final rule to clarify that the requirement to test one blind quality control sample in each analytical run applies to initial validity test runs as well as to initial drug testing if the licensee testing facility does not conduct initial validity and drug testing concurrently. However, if a licensee testing facility conducts initial validity and drug testing of specimens concurrently, the NRC intends that the licensee testing facility would include only one blind performance test sample in the analytical run to meet this requirement as well as the same requirement in § 26.137(e)(6)(v) for drug testing runs. The NRC made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

The NRC also added § 26.137(d)(6) in the final rule to require licensee testing facilities to send 1 out of 10 specimens that test negative on initial validity tests to an HHS-certified

laboratory for initial and, if necessary, confirmatory validity testing. The NRC added this requirement in response to public comments noting inconsistencies in the proposed rule's quality control requirements for validity screening, initial validity testing, and initial drug testing, and for the reasons discussed with respect to the addition of a similar requirement applicable to validity screening testing in § 26.137(b)(3). Adding this provision ensures that licensee testing facilities can assess their rates of false negative initial validity test results and therefore meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section 26.137(e) [Quality control requirements for initial drug tests] amends and combines portions of former Section 2.7(d), 2.7(e)(1), and 2.8(b) in Appendix A to Part 26. The former provisions established quality control requirements for performing initial tests for drugs and drug metabolites at licensee testing facilities. The final rule groups together in one paragraph the requirements that were dispersed throughout the former rule to meet Goal 6 of this rulemaking to improve clarity in the organization of the final rule.

Section 26.137(e)(1) amends the first sentence of former Section 2.7(e)(1) in Appendix A to Part 26 but retains the intent of the former provision as it applies to licensee testing facilities. This provision retains the former requirement that licensee testing facilities may use only immunoassay tests that meet the requirements of the Food and Drug Administration for commercial distribution. The NRC has moved the requirements in the former provision related to initial drug testing at HHS-certified laboratories to § 26.167(d)(1) of Subpart G [Laboratories Certified by the Department of Health and Human Services] of the final rule to improve organizational clarity in the rule.

In addition, § 26.137(e)(1) prohibits licensee testing facilities from relying on drug test results from any tests they may use to perform validity screening tests. The NRC added this prohibition 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 final rule permits licensee testing facilities to use such combination tests as validity screening tests if the tests meet the requirements of § 26.137(b)(1). However, the drug testing capabilities of these tests are not yet sufficiently accurate and sensitive to be used in Part 26 programs, in which licensees and other entities are 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 tests 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 final rule retains the former prohibition on using such tests for drug testing at licensee testing facilities.

The NRC added § 26.137(e)(2) 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 negative and valid by an HHS-certified laboratory. This provision incorporates the related provision from the HHS Guidelines to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. With respect to the proposed rule, the final rule adds a sentence prohibiting licensee testing facilities from retaining any information linking donors to specimens pooled for use in the internal quality control program. The agency added this prohibition in response to a public comment requesting this addition. This change meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.137(e)(3) permits licensee testing facilities to conduct multiple tests of a single specimen for the same drug or drug class. The NRC has revised § 26.137(e)(3) in the final rule, with respect to the proposed rule, to include a more precise description of when multiple initial drug tests on a specimen (also know as rescreening) are permitted. The NRC

added this information in the final rule in response to a comment received on the proposed provision requesting the addition. The requirements in the provision are consistent with a similar provision in the HHS Guidelines and therefore, meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.137(e)(4) amends the first sentence of former Section 2.8(b) in Appendix A to Part 26. The former sentence stated that licensee testing facilities are not required to assess their false positive rates in drug testing. The final rule retains the intent of the former requirement, but the NRC has updated the terminology in the provision to use the new terms that are used throughout the final rule, e.g., “initial” rather than “screening,” as discussed with respect to § 26.5 [Definitions].

Section 26.137(e)(5) amends the second sentence of former Section 2.8(b) in Appendix A to Part 26. This provision required 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 paragraph retains the intent of the former provision but makes several changes to the specific requirements.

The paragraph uses the term “analytical run” rather than the former term “test run” to reflect changes in testing technologies that some licensee testing facilities have adopted since the former rule was published. Requirements for blind performance and other quality control testing in the former 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 final rule uses the term, “analytical run,” to refer to both batch and continuous processing, as defined in § 26.5 [Definitions]. This change has been made to meet Goal 6 of this rulemaking to improve clarity in the language of the final rule.

The former rule did not establish a number or percentage of negative specimens that licensee testing facilities were required to submit to the HHS-certified laboratory for performance testing, which raised implementation questions from licensees who have wanted to know how many specimens must be submitted. Therefore, to clarify the former requirement to "submit a sampling of specimens," the final rule requires 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 final rule also establishes five 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 five percent of an analytical run is a number less than one specimen. In the latter case, the licensee testing facility submits at least one negative specimen from the analytical run. This requirement ensures the ongoing evaluation of the accuracy of the licensee testing facility's initial drug testing without imposing a large performance testing burden.

The NRC has moved the last sentence of the former paragraph, which addressed performance testing of breath analysis equipment for alcohol testing, to § 26.91(e) in Subpart E [Collecting Specimens for Testing] because that subpart of the final rule addresses quality control requirements for alcohol testing. The NRC made this change to meet Goal 6 of this rulemaking to improve clarity in the organization of the final rule.

Section 26.137(e)(6) amends the requirements of former Section 2.8(c) in Appendix A to Part 26 and applies them to licensee testing facilities. The NRC is applying requirements for quality controls to initial drug testing at licensee testing facilities to provide greater assurance that initial drug tests performed by these facilities provide accurate results. The increased performance testing requirements in the final rule are necessary because the final rule permits licensees and other entities to rely on test results from other Part 26 programs to a greater extent that the former rule. Therefore, it is necessary to ensure that any tests performed at

licensee testing facilities meet minimum standards. This change meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

The final rule, with respect to the proposed rule, moves the provision in proposed § 26.137(e)(7) to § 26.137(e)(6) in the final rule to improve organizational clarity. The NRC made this change to address a public comment received on the proposed rule that noted that because the second sentence in proposed § 26.137(e)(7) discussed a quality control sample requirement, the provision would be more appropriately located in § 26.137(e)(6) which describes the quality control sample requirements for each analytical run.

Section 26.137(e)(6) establishes requirements for the number of quality control samples to be included in each analytical run at the licensee testing facility. The final rule requires that a minimum of 10 percent of the specimens in each analytical run must be quality control samples. For example, if an analytical run consists of 50 donor specimens, an additional 5 quality control samples would be included in the analytical run for a total of 55 specimens tested in the run. The licensee testing facility will not send the quality control samples to the HHS-certified laboratory for confirmatory testing, but use them for internal quality control purposes only. The requirements in this paragraph incorporate the related requirements in the HHS Guidelines 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.

The final rule also requires licensee testing facilities to ensure that quality control samples that are positive for each drug and metabolite for which the FFD program conducts testing are included in at least one analytical run in each quarter of the calendar year. The NRC added this provision at the request of comments received addressing inconsistences within the proposed rule. The proposed rule required quality control samples for each type of validity test, but failed to specify the required distribution of quality control samples among the drugs and metabolites for which the FFD program tests. This provision clarifies the former rule

and increases the internal consistency of this subpart. Additionally, this provision provides for enhanced monitoring of the effectiveness of the licensee testing facilities' drug testing procedures to meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

The NRC has added § 26.137(e)(6)(i)–(e)(6)(iii) to describe the required characteristics of the quality control samples that the licensee testing facility must include in each analytical run of specimen testing. These provisions 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 25 percent below the cutoff level for each drug and drug metabolite for which testing is conducted. The final rule, with respect to the proposed rule, revises the requirement that a quality control sample must be targeted at 75 percent of the cutoff level and instead, the final rule requires the calibrator to be targeted at 25 percent below the cutoff level. This change was made to improve the clarity of the language of the final rule without changing the intent of the provision. These requirements are consistent with the current HHS Guidelines for processing quality control samples during initial drug testing.

With respect to the proposed rule, the final rule has added § 26.137(e)(6)(iv) and § 26.137(e)(6)(v) to further enhance quality control requirements for initial drug testing at licensee testing facilities. In response to a public comment, the NRC added § 26.137(e)(6)(iv) to require that each analytical run has a sufficient number of calibrators to ensure linearity of the assay. This additional provision is consistent with the related requirement in the HHS Guidelines. Section 26.137(e)(6)(v) requires that one sample must appear to be a donor sample to the laboratory analysts. This requirement was previously embedded in § 26.137(e)(7) of the proposed rule, and the NRC moved the requirement to § 26.137(e)(6)(v) of the final rule in response to a comment received that noted this move would enhance organizational clarity in the rule. The NRC agrees with the commenter.

Section 26.137(e)(7) extends to licensee testing facilities the requirement in the third

sentence of the last paragraph of former Section 2.8(c) in Appendix A to Part 26. That provision required 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 final rule extends this requirement to licensee testing facilities because it is a standard forensic practice that is necessary to ensure the integrity of the testing process.

The NRC has added § 26.137(f) [Errors in testing] 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 final rule requires the licensee or other entity to document the investigation and any corrective actions taken. The provision requires licensees and other entities to investigate any testing errors or unsatisfactory performance identified throughout the testing process or during the review process that are required under § 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. This provision clarifies that intent. Thorough investigation and reporting of such test results will continue to assist the NRC, the licensees, HHS, and the HHS-certified laboratories in preventing future occurrences.

The NRC has reorganized the requirements in proposed § 26.137(f) into a list format in § 26.137(f)(1)–(f)(5) in the final rule to improve the organizational clarity of the rule and added new requirements to this section for the reasons discussed with respect to each provision.

Section 26.137(f)(1) requires, whenever possible, that the investigation of testing or processing errors must determine relevant facts and identify the root cause(s) of the error. Section 26.137(f)(2) requires the licensee testing facility to take action to correct the cause of any error or unsatisfactory performance within the licensee testing facility’s control.

The NRC has added § 26.137(f)(3) to the final rule, with respect to the proposed rule, to

address instances when testing of a quality control sample at a licensee testing facility yields a false negative test result. This provision requires the licensee testing facility to forward all donor specimens from the analytical run in which the error is detected to the HHS-certified laboratory for additional testing. This requirement is necessary to ensure that licensees and other entities do not permit individuals who may have altered a specimen or used prohibited drugs to be granted or maintain authorization to have the types of access or perform the duties that require them to be subject to the rule. Additional testing at the HHS-certified laboratory of the donor specimens included in the analytical run during which the error is identified ensures that public health and safety and the common defense and security are not placed at risk because initial validity or drug test results from the licensee testing facility failed to identify an individual who has attempted to subvert the testing process or engaged in substance abuse. In addition, testing of these specimens at the HHS-certified laboratory may also provide the licensee testing facility with additional information regarding the cause(s) and extent of condition that resulted in the error. The NRC added this requirement to the final rule to enhance consistency of the rule's requirements for addressing errors in testing at licensee testing facilities with those required for addressing errors in testing at HHS-certified laboratories and in response to public comments received on the proposed rule noting the inconsistencies. This requirement is consistent with standard forensic practices and meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section § 26.137(f)(3) also requires the licensee testing facility to implement corrective actions before resuming testing of donor specimens. For example, if testing of a certified-positive quality control sample at the licensee testing facility yields false negative test results for opiates, this provision requires the licensee testing facility to stop testing donor specimens for opiates until the cause(s) of the false negative test are identified and corrected. Similarly, if a

quality control sample that has been certified to contain an adulterant at a concentration above the cutoff levels established in Subpart F for validity screening or initial validity testing yields a false negative test result, this provision requires the licensee testing facility to stop testing for that adulterant until the cause(s) of the false negative test result are identified and corrected. This requirement is necessary to prevent additional errors in testing that could permit individuals who may have altered a specimen or used prohibited drugs to be granted or maintain authorization to have the types of access or perform the duties that require them to be subject to the rule. The NRC added this requirement to the final rule to enhance consistency of the rule's requirements for addressing errors in testing at licensee testing facilities with those required for addressing errors in testing at HHS-certified laboratories and in response to public comments received on the proposed rule mentioning the inconsistencies. This requirement is consistent with standard forensic practices and meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The NRC has added § 26.137(f)(4) to address instances where testing conducted at an HHS-certified laboratory identifies a specimen that yielded a false negative test result from the licensee testing facility. To evaluate whether tests at a licensee testing facility may be providing false negative test results, § 26.137(b)(3), (d)(6), and (e)(5) require the licensee testing facility to submit some donor specimens that yield negative test results to an HHS-certified laboratory for additional testing. If, after confirmatory testing by the HHS-certified laboratory, a donor specimen yields positive, substituted, adulterated, or invalid results, § 26.137(f)(4) mandates that the licensee testing facility must take corrective action(s) before resuming testing for the drug(s), drug metabolite(s), adulterant(s), or other specimen characteristics (i.e., creatinine, pH) associated with the donor specimen(s) that yielded the false negative result(s). Additionally, § 26.137(f)(4) permits the licensee or other entity to re-collect and test specimens from any

donor whose test results from initial testing at the licensee testing facility may have been inaccurate. The NRC added this provision to the final rule for the same reasons discussed with respect to § 26.137(f)(3).

Section 26.137(f)(5) requires the licensee or other entity to document the investigation and any corrective actions taken for consistency with Criterion XVI in Appendix B to 10 CFR Part 50.

Section 26.137(g) [Accuracy] retains former Section 2.7(o)(3)(i) in Appendix A to Part 26 as it applied to licensee testing facilities. This provision requires checking the instruments used in testing for accuracy. The final rule moves the former requirement as it relates to HHS-certified laboratories to § 26.167(h) in Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity.

Section 26.137(h) [Calibrators and controls] updates former Section 2.7(o)(2) in Appendix A to Part 26, which established 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. This provision updates the former 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 requirements in this paragraph incorporate the related requirements in the HHS Guidelines and meet Goal 1 of this rulemaking 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.

The NRC has added § 26.139 to combine requirements related to the reporting and

management of test results from the licensee testing facility that were interspersed throughout former Appendix A to Part 26. The agency made this change to meet Goal 6 of this rulemaking to improve clarity in the organization of the final rule, by grouping related requirements together in a single section.

Section 26.139(a) amends former Section 2.7(g)(2) in Appendix A to Part 26. That provision established requirements for the manner in which HHS-certified laboratories and licensee testing facilities must report test results to licensee management. The final rule amends the former provision by moving the former requirements that were related to reporting test results from HHS-certified laboratories to § 26.169(b) of Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity. The final rule also deletes the former reference to "special processing" and replaces it with reference to validity test results, consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). The NRC made these changes to improve clarity in the language and organization of the rule consistent with Goal 6 of this rulemaking.

With respect to the proposed rule, the final rule eliminates use of the term "non-negative" in § 26.139(a) for the reasons discussed with respect to § 26.5 [Definitions] for eliminating this term throughout the proposed rule. Eliminating the term "non-negative" and replacing it with terms to describe specific results of drug and validity testing (e.g., "positive," "adulterated"), necessitates splitting the last sentence of proposed § 26.139(a) into two sentences for clarity. Therefore, the final rule prohibits licensee testing facilities from reporting to licensee or other entity management any positive drug test results from initial drug testing at the licensee testing facility, except as permitted under § 26.75(h). The final rule also prohibits licensee testing facilities from reporting to licensee or other entity management any validity screening and initial validity test results that indicate a specimen is of questionable validity and

any positive initial drug test results from specimens that are of questionable validity. The NRC made these changes to improve clarity in the language of the rule, consistent with Goal 6 of this rulemaking.

Section 26.139(b) amends the last sentence of former § 26.24(d)(1), which specified the individuals to whom results of initial tests from the licensee testing facility may be released. The NRC added the MRO's staff to the list of individuals who are 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 final rule. Individuals who are serving as MRO staff members require access to initial test results from a licensee's testing facility in the course of performing their administrative duties for the MRO. Additionally, with respect to the proposed rule, the final rule permits an SAE to access initial test results when appropriate consistent with the addition of this job role to the final rule. Omitting the SAE from this provision was an unintended oversight in the proposed rule which the NRC has corrected in the final rule.

Section 26.139(c) amends former Section 2.7(o)(5) in Appendix A to Part 26. The NRC has moved the requirements in the former paragraph that addressed the availability of personnel to testify in proceedings related to drug test results from an HHS-certified laboratory to § 26.153(f)(2) of Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity. The final rule moves the former requirement for licensee testing facility personnel to be available to testify at any proceedings with respect to breath analysis test results to § 26.85(d) [Personnel available to testify at proceedings] because the collection site and not the licensee testing facility is typically responsible for quality control of alcohol testing equipment. The agency made these changes for organizational clarity in the rule, consistent with Goal 6 of this rulemaking.

Section 26.139(d) amends the portions of former Section 2.7(g)(6) in Appendix A to Part 26 that applied to the summary report that licensee testing facilities must provide to FFD

program management. The NRC has replaced the former requirement for the licensee testing facility to prepare a monthly report of test results with a requirement for the licensee testing facility to summarize the data annually in the FFD program performance report required under § 26.717(b) of the final rule. Experience implementing the former 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 final rule replaces the monthly reporting requirement in former Section 2.7(g)(6) in Appendix A to Part 26 with a requirement in § 26.139(f) of the final rule for FFD program management to monitor the ongoing effectiveness of the licensee testing facility testing program. This change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. The NRC has moved the requirements in the former paragraph that addressed summary reports from HHS-certified laboratories to § 26.169(k) of Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity. With respect to the proposed rule, the agency changed the cross-reference to FFD program performance reporting requirements in § 26.217(b) in the proposed rule to § 26.717(b) in the final rule to reflect the changes the NRC has made in the organization of the final rule.

Section 26.139(e) amends former Section 2.7(g)(7) in Appendix A to Part 26. That provision required licensee testing facilities and HHS-certified laboratories to report test results for both the cutoff levels specified in Part 26 and any more stringent cutoff levels used by the FFD program. The NRC has relocated the former requirement related to HHS-certified laboratories to § 26.169(c) of Subpart G [Laboratories Certified by the Department of Health and Human Services] for organizational clarity. The final rule requires 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 § 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 former 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 final rule eliminates this requirement, because § 26.31(d)(3)(iii)(C) requires a qualified forensic toxicologist to certify the scientific and technical suitability of the licensee's or other entity's testing process at any lower cutoff levels. Therefore, the testing and reporting requirements in the former rule are no longer needed to monitor licensee testing facility performance in this area. The final rule continues 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 § 26.31(b)(1).

Section 26.139(f) has been added to require FFD program management to monitor the ongoing effectiveness of the licensee testing facility testing program. The final rule provides examples of the types of information and possible program performance indicators that licensees and other entities may use for program monitoring. The final rule also requires FFD program management to make adjustments to the testing program in response to information gained from the ongoing monitoring. These requirements replace the monthly summary report required under former 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 paragraph is also consistent with the NRC's performance-based approach to regulation. This change meets Goal 3 of this rulemaking 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.

The NRC has added § 26.151 to introduce the purpose of the 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. Adding this paragraph meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. The majority of the requirements in this subpart are based on the former requirements in Appendix A to Part 26, as they relate to HHS-certified laboratories. However, the rule substantially updates the former requirements to be consistent with the HHS Guidelines.

Section 26.153 Using certified laboratories for testing urine specimens.

The NRC added § 26.153 to group into one section requirements related to the use of HHS-certified laboratories by licensees and other entities who are subject to the rule.

Section 26.153(a) combines and updates former requirements for licensees and other entities to use HHS-certified laboratories for initial and confirmatory drug testing of urine specimens. The paragraph relocates and combines former § 26.24(f), and former Sections 1.1(3), and 4.1(a) in Appendix A to Part 26. These provisions required licensees and other entities to use HHS-certified laboratories for drug testing. The NRC made this change to eliminate redundancies in the former rule and improve organizational clarity. The paragraph updates the former citations for the HHS Guidelines because the guidelines have been amended several times since the former rule was published. In addition, the provision provides current contact information for obtaining information about the certification status of HHS-certified laboratories because the contact information has changed since the former rule was published. The paragraph also adds 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 rule, as discussed with respect to

§ 26.31(d)(3)(i). The rule also updates the cross-reference to former § 26.24(d), which permitted licensee testing facilities to conduct initial drug tests, to reference the related provision in the final rule, § 26.31(d)(3)(ii).

Section 26.153(b) amends the first sentence of former Section 2.7(l)(2) in Appendix A to Part 26. The former provision required 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 former requirement for HHS-certified laboratories to be capable of conducting confirmatory alcohol testing of blood has been deleted for the reasons discussed with respect to § 26.83(a). The paragraph adds 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 rule, as discussed with respect to § 26.31(d)(3)(i). The second sentence of former Section 2.7(l)(2) in Appendix A to Part 26, which established requirements for the capabilities of licensee testing facilities, has been moved to § 26.123 of Subpart F [Licensee Testing Facilities] for organizational clarity. The agency deleted the last sentence of the former paragraph, which permitted the testing of breath specimens for alcohol at the collection site, because the rule addresses alcohol testing in Subpart E [Collecting Specimens for Testing]. These organizational changes to the former paragraph have been made to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.153(c) amends the first sentence of former Section 2.7(k) in Appendix A to Part 26. The former provision prohibited HHS-certified laboratories from subcontracting unless authorized by the licensee. The rule extends this restriction to subcontracting for specimen validity testing for consistency with the addition of requirements to perform validity testing to the rule, as discussed with respect to § 26.31(d)(3)(i). The second sentence of former

Section 2.7(k) has been deleted from the paragraph for several reasons: First, the requirement to have the capability to test for marijuana, cocaine, opiates, phencyclidine, and amphetamines has been deleted because it is redundant with § 26.31(d)(1). The requirement to be capable of testing whole blood has been deleted because the rule no longer permits donors to request confirmatory alcohol testing of blood for the reasons discussed with respect to § 26.83(a). Finally, the requirement for laboratories to be capable of conducting GC/MS testing has been eliminated because HHS-certified laboratories would be permitted to use other methods of confirmatory testing, consistent with related revisions to the HHS Guidelines.

Section 26.153(d) amends former Section 4.1(b) in Appendix A to Part 26, which required 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 final rule eliminates reference to testing for blood in this provision because the rule no longer permits donors to request confirmatory alcohol testing of blood for the reasons discussed with respect to § 26.83(a).

Section 26.153(e) amends the third sentence of former Section 2.7(m) in Appendix A to Part 26. That sentence required 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 former 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 paragraph revises the former requirement to indicate that licensees and other entities are 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 rule clarifies that the pre-award inspection and

evaluation must be performed by qualified individuals.

Section 26.153(e) also permits 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 rule requires that the replacement laboratory must be in use by another Part 26 program. The rule adds this provision to ensure that testing can continue, in the event that the HHS-certified laboratory on whom a licensee or other entity relies loses its certification, as some licensees have experienced. Related requirements for auditing the replacement laboratory are specified in § 26.41(g)(5).

The agency added § 26.153(f) 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.

Section 26.153(f)(1) retains the requirement in former Section 2.7(l)(1) in Appendix A to Part 26. The former requirement stated that HHS-certified laboratories must comply with applicable State licensor requirements. The final rule replaces 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 clarification is 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 are required to meet the requirements of that State. The NRC made this change for clarity in the language of the rule as well as consistency with the HHS Guidelines.

Section 26.153(f)(2) amends former Section 2.7(o)(5) in Appendix A to Part 26. The former regulation required HHS-certified laboratories to make available qualified personnel to

testify in proceedings based on urinalysis results reported by the laboratory. The NRC moved the reference to licensee testing facilities to § 26.139(c) in 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 has been moved to § 26.85(d) in Subpart E [Collecting Specimens for Testing] for organizational clarity and because responsibility for testifying with respect to breath analysis results resides with the licensee's or other entity's collection site personnel.

Section 26.153(f)(3) updates former Section 3.1 in Appendix A to Part 26, which required HHS-certified laboratories to protect donors' records. The former requirement for licensee testing facilities to protect donors' records has been subsumed within the second sentence of § 26.37(a) for organizational clarity. The cross-reference to former § 26.29 has been updated to reference § 26.39 in the final rule.

Section 26.153(f)(4) updates former Section 3.2 in Appendix A to Part 26. Specifically, the rule adds a reference to Sec. 503 of Pub. L. 100-71 to document the basis for this requirement. The paragraph adds 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 rule, as discussed with respect to § 26.31(d)(3)(i). The paragraph deletes the former reference to records related to alcohol test results because the final rule will no longer require HHS-certified laboratories to be capable of testing blood specimens for alcohol, as discussed with respect to § 26.83(a). With respect to the proposed rule, the NRC has added a phrase to the provision to clarify that a donor’s designated representative is also permitted to have access to records relating to the donor’s validity test results. The NRC made this change in response to a public comment requesting the clarification.

The NRC added § 26.153(f)(5) 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 final rule, with respect to the proposed rule, adds a reference to provisions added in the final rule at § 26.183(b) to specify specific conflict of interest relationships. The NRC added the provisions in § 26.183(b) in response to a comment on the proposed rule requesting the NRC to consider using the examples of MRO conflict of interest relationships specified in DOT's drug and alcohol testing regulations. The paragraph responds 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 is warranted to prevent potential conflict of interest concerns. The paragraph is consistent with the related provision in the HHS Guidelines.

Section 26.153(f)(6) amends the requirements in the first two sentences of former Section 2.7(m) in Appendix A to Part 26, which required HHS-certified laboratories to permit the NRC, licensees, and other entities to conduct inspections at any time, including unannounced inspections. The rule deletes, for organizational clarity, the existing references to collection site services and licensee testing facilities, which are covered under Subpart F. The paragraph also deletes reference to confirmatory testing of blood specimens for alcohol because HHS-certified laboratories are no longer testing blood specimens for alcohol, as discussed with respect to § 26.83(a).

A new § 26.153(g) requires 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 paragraph is necessary to prevent licensee and other entity specimens from being rejected.

Section 26.155 Laboratory personnel.

Section 26.155 updates former Section 2.5 in Appendix A to Part 26 to be consistent with revisions to the HHS Guidelines.

Section 26.155(a) [Day-to-day management of the HHS-certified laboratory] amends former Section 2.5(a)(1) in Appendix A to Part 26, which required the HHS-certified laboratory to have a qualified individual to assume responsibility for day-to-day management of the HHS-certified laboratory. Specifically, the paragraph replaces the term "qualified individual" with the term "responsible person" for consistency with terminology that other Federal agencies use to refer to this job role. The final rule retains the majority of Section 2.5(a)(2) in Appendix A to Part 26 and establishes qualification requirements for the responsible person. The provisions in § 26.155(a)(1)(i)–(a)(1)(iv) retain former Section 2.5(a)(2)(i)–(a)(2)(iv) in Appendix A to Part 26, with minor grammatical changes that are consistent with similar changes to the related provisions in the HHS Guidelines.

Section 26.155(a)(2) and (a)(3) establishes minimum day-to-day management responsibilities of the responsible person and retains former Section 2.5(a)(4) and (a)(5) in Appendix A to Part 26.

Section 26.155(a)(4) retains former Section 2.5(a)(5) in Appendix A to Part 26, which relates to the responsible person's responsibility to maintain the HHS-certified laboratory procedures in a manual. With respect to the proposed rule, the final rule includes a provision that HHS-certified laboratories' procedures be maintained in a manual of standard operating procedures. The proposed rule eliminated the former requirement in Section 2.5(a)(5) to provide flexibility to HHS-certified laboratories in how laboratory operating procedures were maintained. However, based on a comment received on the proposed rule, the NRC has re-instituted the former requirement that laboratory procedures be maintained in a manual to improve consistency with the HHS Guidelines, meeting Goal 1 of this rulemaking. The

paragraph retains the former requirements in the second and third sentences of Section 2.5(a)(5) in Appendix A to Part 26, and requires 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. The responsible person must also maintain copies of the procedures. The final rule updates the former cross-reference to Section 2.7(o) in Appendix A to Part 26 to reference § 26.157, consistent with the organizational changes made to the rule.

Section 26.155(a)(5) and (a)(6) retains former Section 2.5(a)(6) and (a)(7) in Appendix A to Part 26. These provisions define the responsible person's responsibilities with respect to maintaining a quality assurance program and taking remedial actions to maintain satisfactory laboratory operations.

Section 26.155(b) [Certifying scientist] amends former 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 rule provides more detailed requirements with respect to the individual who certifies test results at the HHS-certified laboratory before they are transmitted to the licensee or other entity's MRO.

In § 26.155(b)(1), a new job title, "certifying scientist," replaces the term "qualified individual(s)" in the first sentence of former Section 2.5(b) in Appendix A to Part 26 for consistency with a related change in the HHS Guidelines. The final rule, with respect to the proposed rule, replaces the phrase “attest the validity of” with “certify” test results, as this is a more accurate description of the responsibilities of a certifying scientist. The NRC made this change in response to a comment received on the proposed rule. Section 26.155(b)(2) specifies the required qualifications of individuals who serve as certifying scientists. Section 26.155(b)(3) permits laboratories to use more than one certifying scientist with differing responsibilities.

Section 26.155(c) [Day-to-day operations and supervision of analysts] retains former Section 2.5(c) in Appendix A to Part 26. The rule makes minor language changes to the former paragraph to increase the consistency of the language in this provision with that of the related provision in the HHS Guidelines.

Section 26.155(d) [Other personnel] and (e) [Training] retains former Section 2.5(d) and (e) in Appendix A to Part 26, respectively.

Section 26.155(f) [Files] updates former Section 2.5(f) in Appendix A to Part 26. The revisions are consistent with related requirements in the HHS Guidelines.

Section 26.157 Procedures.

Section 26.157 reorganizes and amends requirements for HHS-certified laboratories' procedures. The requirements for procedures were interspersed throughout former Appendix A to Part 26, including requirements contained in former Sections 2.2 and 2.7 in Appendix A to Part 26. The NRC has combined procedural requirements for the laboratories into a single section to improve organizational clarity in the rule.

In § 26.157(a), the agency has made minor editorial changes to the first sentence of former Section 2.2 in Appendix A to Part 26, but retains the former requirement for HHS-certified laboratories to have detailed procedures for conducting testing. The rule deletes the former reference to blood samples because donors no longer have the option to request blood testing for alcohol, as discussed with respect to § 26.83(a). Reference to licensee testing facilities has been moved to § 26.127(a) in Subpart F [Licensee Testing Facilities] for organizational clarity. The rule also deletes reference to procedures for specimen collections, because the NRC relocated procedural requirements for specimen collections to Subpart E [Collecting Specimens for Testing] in the final rule.

Section 26.157(b) combines and amends portions of the requirements in the first

sentence of former 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 regulation retains the portions of the former paragraphs that required 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 former requirements related to licensee testing facilities have been moved to § 26.127(b) in Subpart F [Licensee Testing Facilities] for organizational clarity. The rule also removes references to custody-and-control procedures for blood specimens because donors no longer have the option to request blood testing for alcohol, as discussed with respect to § 26.83(a).

The NRC has amended the portions of former Section 2.7(o)(1) in Appendix A to Part 26 that address the required content of procedures for HHS-certified laboratories. Section 26.157(c) retains the portions of the former provision that required laboratories to develop and maintain written 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 paragraph presents the required topics of the procedures in a list format in § 26.157(c)(1) through (c)(12) to clarify that each topic stands on its own. For organizational clarity, two portions of the former provision have been moved to other subparts of the rule that address related topics. The NRC relocated requirements for licensee testing facility procedures to § 26.127(c) in Subpart F [Licensee Testing Facilities]. In addition, the rule moves the last two sentences of former Section 2.7(o)(1), which specify records retention requirements, to § 26.715(b)(4) of Subpart N [Recordkeeping and Reporting Requirements].

Section 26.157(d) amends former Section 2.7(o)(3)(iii) in Appendix A to Part 26. The final (and former) provision 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 rule makes three changes to the former provision for organizational clarity. The paragraph presents the required topics of the procedures in a list format in § 26.157(d)(1)–(d)(3) to clarify that each topic stands on its own. The former requirement to maintain records of preventative maintenance has been relocated to § 26.715(b)(10) in Subpart N [Recordkeeping and Reporting Requirements]. And, the rule moves the former requirements that apply to licensee testing facilities to § 26.127(d) in Subpart F [Licensee Testing Facilities].

Section 26.157(e) amends former Section 2.7(o)(4) in Appendix A to Part 26, but continues to require documented corrective actions if systems are out of acceptable limits or errors are detected. The requirements in the former paragraph that apply to licensee testing facilities have been moved to § 26.127(e) in Subpart F for organizational clarity.

Section 26.159 Assuring specimen security, chain of custody, and preservation.

The NRC added § 26.159 to present in one section the requirements of the rule that apply to HHS-certified laboratories with respect to the safeguarding of specimen identity, integrity, and security. This organizational change consolidates requirements that were dispersed throughout the former rule.

Section 26.159(a) amends former Section 2.7(a)(1) in Appendix A to Part 26. This provision retains the first three sentences of former Section 2.7(a)(1) in Appendix A to Part 26, which required HHS-certified laboratories to be secure and accessible only to authorized personnel. For organizational clarity, the NRC moved the requirements that apply to licensee testing facilities to § 26.129(a) in Subpart F [Licensee Testing Facilities]. The last sentence of the former paragraph, which establishes recordkeeping requirements, has been moved to § 26.715(b)(13) in Subpart N [Recordkeeping and Reporting Requirements]. In addition, the

NRC has revised the last sentence of the former paragraph to increase clarity in the requirement and expands the list of persons who are authorized to have access to the laboratory to include representatives of the Secretary of HHS and emergency responders. This change increases the consistency of Part 26 with the related provision in the HHS Guidelines.

Section 26.159(b) amends former Section 2.7(b)(1) in Appendix A to Part 26. That provision established requirements for receiving specimens at the HHS-certified laboratory and assuring their integrity and identity. The final rule makes several organizational changes to the former rule by dividing the provision into paragraphs § 26.159(b)(1) and (b)(2) for increased organizational clarity.

Section 26.159(b)(1) retains the former 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 rule moves the former requirements related to licensee testing facilities to § 26.129(b) in Subpart F [Licensee Testing Facilities] for organizational clarity. With respect to the proposed rule, the final rule adds several requirements to the provision.

The NRC has renumbered as § 26.159(b)(1)(i), but retained without change, the portion of proposed § 26.159(b)(1) that required 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 will depend on the nature of the tampering identified as a result of the investigation. For example, if the investigation indicates that the tampering was an attempt to subvert the testing process and the persons involved are identified, the rule requires licensee and other entity management personnel to impose the sanctions in § 26.75(b) for a subversion attempt.

Section 26.159(b)(1)(ii) requires the licensee and other entity to collect another

specimen as soon as possible, if the licensee or other entity has reason to question the integrity and identity of a specimen. With respect to the proposed rule, the final rule eliminates the need to collect another specimen if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. If this circumstance arises and the licensee testing facility has retained the specimen in Bottle B and it is intact, the rule requires the licensee testing facility to forward the intact specimen for testing to the HHS-certified laboratory. The NRC added this provision to the final rule in response to public comments on the related provision in the proposed rule. The commenters requested the NRC to include this provision from DOT's procedures. The NRC agreed with the commenters' suggestion because eliminating the recollection when an intact specimen is available reduces the burden on donors that a recollection would impose.

The final rule, with respect to the proposed rule, establishes a new section, § 26.159(b)(2). to specify the exclusive grounds requiring an MRO to cancel a test. The NRC added this section in response to public comments received on the proposed rule that requested this clarification. Section 26.159(b)(2)(i) requires the MRO to cancel a test if the custody and control form does not contain information to identify the specimen collector and the collection site cannot provide conclusive evidence of the collector's identity. Section 26.159(b)(2)(ii) requires the MRO to cancel a test if the identification numbers on the specimen bottle seal(s) do not match the identification numbers on the custody-and-control form. Section 26.159(b)(2)(iii) requires the MRO to cancel a test if a specimen bottle seal is broken or shows evidence of tampering and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist. Section 26.159(b)(2)(iv) requires the MRO to cancel a test if the specimen appears to have leaked out of its sealed bottle and there is less than 15 mL remaining, and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist. Section 26.159(b)(2)(v) requires the MRO to cancel a test if the provisions of

§ 26.165(f)(2) apply. The NRC incorporated these requirements from the related DOT procedures.

Section 26.159(c) updates and combines former Section 2.7(b)(2) in Appendix A to Part 26 with portions of former Sections 2.7(n) and 3.1 in Appendix A to Part 26. These regulations in the former rule established requirements for chain-of-custody procedures for specimens and aliquots at licensee testing facilities and HHS-certified laboratories. For organizational clarity, the NRC has relocated the requirements in the former paragraphs that are related to licensee testing facilities to § 26.129(c) in Subpart F [Licensee Testing Facilities]. The final rule retains the requirements in former Sections 2.7(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 NRC made these changes to reduce redundancies and improve the organizational clarity of the rule.

Section 26.159(d) and (e) updates the portions of former Section 2.7(a)(2) in Appendix A to Part 26 that established requirements for HHS-certified laboratory personnel to maintain and document the chain of custody for specimens and aliquots, by replacing the former paragraph with two related provisions from the HHS Guidelines. Paragraph (d) in this section requires the laboratory's internal custody-and-control form to allow for identification of the donor, documentation of the testing process and transfers of custody of the specimen. The agency added the phrase, "within the laboratory," to paragraph (e) of this section to clarify that the requirement to document each instance of handling and transfer of specimens applies to internal laboratory activities and does not apply to transfers involving couriers. For organizational clarity, the rule relocates the requirements in the former paragraph that are related to licensee testing facilities to § 26.129(d) and (e) in Subpart F [Licensee Testing Facilities].

Section 26.159(f) and (g) separates former Section 2.4(i) in Appendix A to Part 26 into

two paragraphs, for the reasons discussed with respect to the similar provisions of § 26.117(i) and (k) and § 26.129(g) and (h). The paragraphs repeat the requirements for packaging and shipping positive, adulterated, substituted, or invalid specimens that have been presented in § 26.117(i) and (k) of Subpart E [Collecting Specimens for Test] 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 § 26.117(i) and (k). With respect to the proposed rule, the final rule clarifies § 26.159(f) to ensure that a copy of the custody-and-control form, rather than the original custody-and-control form, is included with an aliquot of a single specimen or Bottle B of a split specimen that is transferred to a second HHS-certified laboratory for testing. The NRC made this change in response to a public comment on this provision that noted the proposed provision was inconsistent with the related requirement in the HHS Guidelines.

Section 26.159(h) replaces former Section 2.7(c) in Appendix A to Part 26. The former provision established requirements for refrigerating urine specimens at the HHS-certified laboratory and licensee testing facility to protect them from degradation. The rule replaces the former paragraph with the simplified language of the related provision in the HHS Guidelines. The NRC moved the requirements related to short-term refrigerated storage at licensee testing facilities to § 26.129(f) in Subpart F [Licensee Testing Facilities] for organizational clarity. The final rule, with respect to the proposed rule, adds the Fahrenheit temperature level that is equivalent to the Celsius temperature level included in the proposed rule in to improve the clarity of the final rule.

In § 26.159(i), the NRC amends former Section 2.7(h) in Appendix A to Part 26. The former requirement established requirements for long-term frozen storage of positive urine specimens at HHS-certified laboratories and licensee testing facilities. For organizational clarity, the NRC moved the requirements related to long-term storage of specimens by licensee

testing facilities to § 26.135(c) in Subpart F [Licensee Testing Facilities]. The rule adds requirements for storing specimens that yield adulterated, substituted, or invalid test results from specimen validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). The NRC has eliminated the reference to "administrative or disciplinary proceedings" in the first sentence of the former paragraph because there are other circumstances in which it may be necessary to have a specimen available for retesting, including, but not limited to, retesting an aliquot of an invalid specimen at a second HHS-certified laboratory under § 26.161(g). The rule also updates the terminology used in the former paragraph by adding a reference to "Bottle B" of a split specimen. As discussed with respect to § 26.5 [Definitions], these changes in terminology are intended to improve clarity in the language of the rule.

The NRC added § 26.159(j) to incorporate related changes to the HHS Guidelines. The final rule permits the HHS-certified laboratory to discard negative specimens. This paragraph also permits 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. With respect to the proposed rule, the final rule prohibits the laboratory from retaining any information linking donors to specimens that are pooled for use in the laboratory's internal quality control program. The NRC added this prohibition in response to a public comment received on the proposed rule. This addition meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.161 Cutoff levels for validity testing.

A new § 26.161 establishes 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 rule, as discussed with respect to § 26.31(d)(3)(i). The rule incorporates these requirements from the HHS Guidelines as revised on April 13, 2004, (69 FR 19644) to meet, in part, Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. This section prohibits licensee and other entities from using more stringent validity test cutoff levels to ensure consistency among licensees and other entities and reduce the likelihood of false adulterated, substituted, or invalid test results, and ensure that donors are not subject to sanctions on the basis of inaccurate test results. The prohibition supports Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

The NRC added § 26.161(a) to specify that HHS-certified laboratories must conduct initial and, if necessary, confirmatory validity testing using two different aliquots of a urine specimen. This provision incorporates the related provision from the HHS Guidelines. With respect to the proposed rule, the final rule revises the provision to clarify that confirmatory testing of a second aliquot is required if initial validity test results indicate that the specimen may be adulterated, substitute, dilute, or invalid. The final rule also adds a requirement that licensees and other entities must ensure that the HHS-certified laboratory is capable of conducting, and conducts, confirmatory testing for at least one oxidizing adulterant and any other adulterants for which the licensee's or other entity's FFD program conducts testing. The agency made these changes in response to public comments and to improve clarity in the language of the rule.

The agency added § 26.161(b) to establish requirements and cutoff levels for initial validity tests to be performed at HHS-certified laboratories. With respect to the proposed rule, the final rule renumbers these paragraphs to improve the organization and clarity of the rule. Section § 26.161(b)(1) through (b)(5) establishes requirements for initial validity tests that HHS-

certified laboratories must conduct on a primary specimen. The primary specimen is 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 will determine the creatinine concentration of each specimen under § 26.161(b)(1). If the creatinine concentration is less than 20 mg/dL, the laboratory will determine the specimen's specific gravity under § 26.161(b)(2). Section § 26.161(b)(3) requires the laboratory to determine each specimen's pH. Section §26.161(b)(4) requires the laboratory to test the specimen for the presence of oxidizing adulterants, and § 26.161(b)(5) requires additional validity testing, depending on the characteristics of the specimen.

With respect to the proposed rule, the final rule deletes proposed § 26.161(b)(2). The proposed paragraph specified the results from initial validity testing that would indicate the need for the HHS-certified laboratory to conduct confirmatory validity testing. The NRC deleted this paragraph in the final rule because the criteria it contained repeated the criteria embedded in § 26.161(c)–(f). In addition, the HHS Guidelines do not include these criteria separately. Therefore, this revision increases the consistency of Part 26 with the related provisions in the HHS Guidelines.

The final rule adds § 26.161(c) 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. Section 26.161(c)(1) through (c)(8) specifies results from initial and confirmatory validity testing that indicate that a specimen is adulterated. The paragraphs also specify the appropriate testing devices and instruments to be used for initial and confirmatory validity tests. In general, the paragraphs 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 inconsistent with human physiology; or (3) it presents an acid/base balance (pH) that appears to be inconsistent with human life. The paragraphs 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 specimen 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 methods to detect them have been developed and implemented by HHS-certified laboratories. Section § 26.161(c)(8) recognizes that new adulterants will be found and, therefore, requires 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.

Section 26.161(d) and (e) establishes cutoff levels and criteria for a determination by the laboratory that a specimen has been substituted or is dilute, respectively. In § 26.161(d), the HHS-certified laboratory will 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 1.0010 or equal to or greater than 1.0200. These low creatinine concentrations combined with the highly skewed specific gravity values indicate that the specimen is not human urine. In § 26.161(e), the HHS-certified laboratory is required to report to the MRO that a specimen is dilute if the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specimen specific gravity is greater than 1.0010 but less than 1.0030.

The NRC added § 26.161(f)(1) through (f)(12) to establish the criteria that HHS-certified

laboratories 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-inflammatory drugs 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 that the laboratory could not specifically identify with "scientific certainty" which is 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 rule adopts the term "invalid specimen" with the same meaning.

The rule adds § 26.161(g) to address circumstances in which an HHS-certified laboratory suspects that a specimen is adulterated but cannot identify the adulterant. The paragraph permits 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 will consult with the licensee's or other entity's MRO to determine whether to transfer the specimen to a second laboratory for additional testing.

The agency added § 26.161(h) 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 rule does not permit an FFD program to establish

more stringent cutoff levels for validity testing. The prohibition is necessary to decrease the risk of obtaining false adulterated, substituted, or invalid 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.

Section 26.163 groups together in one section, for organizational clarity, the requirements for conducting initial and confirmatory tests for drugs and drug metabolites at HHS-certified laboratories. The section also updates requirements related to cutoff levels for drugs and drug metabolites in the former rule to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.163(a) [Initial drug testing] amends former 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), § 26.163(a)(1) requires HHS-certified laboratories to apply the same cutoff levels that licensee testing facilities are required to use in § 26.133, except if the FFD program specifies more stringent cutoff levels or the specimen is dilute, as discussed further in § 26.163(a)(2). The paragraph reiterates the former permission for licensees and other entities to establish lower cutoff levels. In addition, § 26.163(a)(1) decreases the initial test cutoff level for marijuana metabolites from 100 nanograms (ng) per milliliter (mL) to 50 ng/mL and increases the initial test cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL for the reasons discussed with respect to § 26.133. The changes are consistent with the HHS cutoff levels for the same substances.

A new § 26.163(a)(2) establishes 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 rule adds special testing procedures and criteria for determining which dilute specimens must be subject to confirmatory drug testing. With respect to the proposed rule, the NRC has eliminated the optional provision for FFD programs to test specimens with initial validity test results that indicate a specimen is dilute using FDA approved kits for the lowest concentration levels marketed for the technologies being used to conduct initial testing of specimens for drug or drug metabolites. This change is based on a comment received on the proposed provision. Instead, the NRC is adopting the procedure proposed by the commenter. That is, for dilute specimens, the final rule permits an FFD program to request the HHS-certified laboratory to conduct confirmatory testing of dilute specimens at the confirmatory assay's LOD for a drug or drug class, if the response to the initial drug test for any drug class for which testing is performed is within 50 percent of the cutoff calibrator level. The NRC agrees that the commenter's approach is consistent with the intent of the proposed provision, while reducing the burden on HHS-certified laboratories imposed by the proposed requirements. This special processing of dilute specimens increases the likelihood that any drugs and drug metabolites in the specimen will be detected. Therefore, this requirement meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs, by increasing the likelihood that testing of dilute specimens will reveal drug use if the donor had engaged in substance abuse.

As discussed with respect to § 26.133, the final rule eliminates the requirement in the last sentence of former Section 2.7(e)(1) of Appendix A to Part 26 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 former 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 rule eliminates this requirement, because § 26.31(d)(3)(iii)(C) requires a qualified forensic toxicologist to certify the scientific and technical validity of any testing at lower cutoff levels. Therefore, the former reporting requirement is no longer needed to ensure laboratory performance in this area. Eliminating this requirement meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

The rule also eliminates former Section 2.7(e)(2) in Appendix A to Part 26. The former provision stated that the list of substances and cutoff levels contained in Appendix A to Part 26 were subject to change by the NRC. At the time the former rule was published, the NRC expected to be able to amend the list of substances and cutoff levels in the former rule without additional rulemaking. However, the NRC has determined that rulemaking is required to make such changes. Therefore, the rule deletes this paragraph because it is unnecessary.

The final rule replaces former Section 2.7(f) in Appendix A to Part 26 with § 26.163(b) [Confirmatory drug testing]. The former provision established cutoff levels and requirements related to confirmatory testing for drugs and drug metabolites at the HHS-certified laboratory. The rule also makes a number of changes to the former paragraph.

The agency has moved former Section 2.7(f)(1) in Appendix A to Part 26 to § 26.169(b)(1) of the final rule. Former Section 2.7(f)(1) required 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. The NRC moved this requirement to § 26.169(b)(1) for organizational clarity because § 26.169 addresses the topic of reporting test results by the HHS-certified laboratory to the MRO.

The NRC has also eliminated the requirement in former 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 former 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 rule eliminates this requirement, because § 26.31(d)(3)(iii)(C) requires 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 is no longer needed to assure laboratory performance in this area.

For organizational clarity, the NRC has moved the first sentence of former Section 2.7(f)(2) in Appendix A to Part 26 that required the laboratory to use GC/MS techniques for confirmatory testing to § 26.167(e)(1) in the final rule. Section § 26.167(e)(1) addresses quality control requirements for conducting confirmatory drug tests.

The rule eliminates former Section 2.7(f)(3) in Appendix A to Part 26. The former provision required HHS-certified laboratories to use GC analysis of blood specimens in testing for alcohol. The final rule also eliminates the confirmatory alcohol cutoff level in former Section 2.7(f)(1) in Appendix A to Part 26. The NRC eliminated these provisions because the rule no longer permits donors to request confirmatory testing of a blood specimen for alcohol, as discussed with respect to § 26.83(a).

In addition, the rule eliminates former Section 2.7(f)(4) in Appendix A to Part 26 for the same reasons discussed with respect to former Section 2.7(e)(2) in Appendix A to Part 26.

Section 26.163(b)(1) amends several of the cutoff levels in former 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 rule increases the confirmatory test cutoff levels for morphine

and codeine to 2,000 ng/mL. This change in the cutoff level for opiate metabolites substantially reduces the number of positive opiate test results that are reported to MROs by HHS-certified laboratories that MROs ultimately verify as negative and is consistent with the opiate cutoff levels contained in the HHS Guidelines.

Section 26.163(b)(1) also amends two of the testing procedures in former Section 2.7(f) in Appendix A to Part 26. The rule amends former Section 2.7(f)(5) in Appendix A to Part 26, which required the laboratory to test for 6-acetylmorphine (6-AM) if a specimen tests positive for opiates on the initial drug test. The rule requires 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 establishes a cutoff level of 10 ng/mL for determining that a specimen is positive for 6-AM. In addition, § 26.163(b)(1) adds a requirement that a specimen must also 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 changes are consistent with the related provisions in the HHS Guidelines.

Section 26.163(b)(1) updates the terminology used in former Section 2.7(f)(1) in Appendix A to Part 26. As discussed with respect to § 26.5 [Definitions], the final rule replaces the term "presumptive positive" with the phrase "positive on an initial drug test" to increase clarity in the language of the rule.

A new § 26.163(b)(2) amends the second sentence of former Section 2.7(f)(2) in Appendix A to Part 26. The former sentence required 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 rule replaces the former sentence with a 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 change has been made to meet

Goal 1 of this rulemaking 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.

Section 26.165 reorganizes and amends the requirements formerly found in § 26.24(f), and Section 2.7(i) and (j) in Appendix A to Part 26 that related to testing split specimens and retesting specimens at HHS-certified laboratories. For organizational clarity, the final rule groups the requirements together in a single section to make them easier to locate in the rule. The section also adds several new requirements.

Section 26.165(a) [Testing split specimens] combines and amends former § 26.24(f) and Section 2.7(j) in Appendix A to Part 26. Those provisions established requirements for HHS-certified laboratories when testing split specimens. The final rule uses 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 rule. The rule also requires specimen validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i).

Section 26.165(a)(1) retains the portions of former Section 2.7(j) in Appendix A to Part 26 that required the HHS-certified laboratory to analyze the primary specimen of a split specimen. The former requirements related to licensee testing facilities in this section have been moved to § 26.135 in Subpart F [Licensee Testing Facilities] for organizational clarity. This paragraph retains the former requirement that the primary specimen (Bottle A) must be subject to initial testing by the HHS-certified laboratory, and confirmatory testing, if the results of initial testing indicate that the specimen is positive. The final rule adds a requirement for HHS-certified laboratories also to conduct initial and, if necessary, confirmatory validity testing of the specimen in Bottle A of a split specimen.

Section 26.165(a)(2) retains the portion of the second sentence of former § 26.24(f) that required the HHS-certified laboratory to perform initial and confirmatory tests, if required, on the primary specimen in Bottle A, even if a licensee testing facility conducted initial testing on an aliquot of the specimen. The NRC moved the former requirement to this section for organizational clarity. With respect to the proposed rule, the final rule replaces the term "non-negative" in the proposed rule with the more specific terms "positive" and "of questionable validity" to refer to the results of testing at the licensee testing facility. The agency made this change to improve the clarity of the rule's language.

Section 26.165(a)(3) retains the authorization in the second sentence of former Section 2.7(j) in Appendix A to Part 26 for licensee testing facilities 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 final rule also retains the former authorization for the specimens in Bottle A and Bottle B to be discarded if test results from the HHS-certified laboratory are negative. With respect to the proposed rule, the final rule makes minor editorial changes to this provision to increase the clarity of the language. In addition, the final rule adds cross-references to § 26.135(a) and (c). These provisions contain requirements for storing Bottle B of a split specimen at a licensee testing facility, if the licensee testing facility chooses to retain Bottle B rather than forwarding it with Bottle A to the HHS-certified laboratory. The NRC made these changes to improve clarity in the language of the rule and in response to a public comment requesting the clarifications.

The NRC added § 26.165(b) [Donor request to MRO for a retest of a single specimen or testing Bottle B of a split specimen] to permit donors to request retesting of an aliquot from a single specimen, if the FFD program does not follow split specimen procedures, and testing of Bottle B if the program follows split specimen procedures. This paragraph assures that donors who are subject to a program that does not follow split specimen procedures have the right to

request additional testing. With respect to the proposed rule, the final rule combines and reorganizes the provisions in proposed § 26.165(b) pertaining to a donor's request for retesting a single specimen with those in proposed § 26.165(c) pertaining to a donor's request for testing of Bottle B of a split specimen. The agency made these changes in response to a public comment. The commenter noted that the separate paragraphs in the proposed rule contained redundant requirements and that separating the requirements into two paragraphs was inconsistent with the related provisions in the HHS Guidelines. Therefore, the NRC also changed the title of this section from "Donor request to MRO for a retest of a single specimen" in the proposed rule to "Donor request to MRO for a retest of a single specimen or testing of Bottle B of a split specimen" in the final rule.

Section 26.165(b)(1) assures that donors may request through the MRO additional testing of an aliquot from a single specimen or testing of Bottle B by a second HHS-certified laboratory. This permission is consistent with related provisions in the HHS Guidelines and amends the requirements in former Section 2.7(j) in Appendix A to Part 26 that pertained to donor requests to test the specimen in Bottle B. The final rule permits donors to request retesting of an aliquot of a single specimen by a second HHS-certified laboratory to protect donors' rights to retesting under FFD programs that do not follow split specimen procedures. The rule adds confirmed adulterated and substituted validity test results as bases for a donor request for testing the specimen in Bottle B or retesting an aliquot of a single specimen, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to §26.31(d)(3)(i). However, in order to have sufficient urine to support retesting, the paragraph applies only if the donor had originally submitted a specimen of 30 mL or more in a single specimen, or a specimen in Bottle A. Specimens that the HHS-certified laboratory determines to be invalid are 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 procedures for requesting and conducting the retest of a single specimen are consistent with those for requesting and conducting tests on the specimen in Bottle B of a split specimen in the final rule.

Section 26.165(b)(2) adds a requirement for the MRO to inform the donor that he or she may, within 3 business days of notification by the MRO of a confirmed positive, adulterated, or substituted test result, request a retest of an aliquot of a single specimen or, as appropriate, Bottle B of a split specimen. The NRC also added a requirement that the donor must request retesting an aliquot of a single specimen or testing the Bottle B specimen within 3 business days after notification by the MRO that a single specimen or the specimen in Bottle A of a split specimen has yielded positive, adulterated, or substituted test results. Since 1994, the HHS Guidelines have allowed up to 72 hours for a donor to make this request, so this change increases the consistency of Part 26 with the HHS Guidelines. This provision combines proposed § 26.165(a)(4) and (b)(1) into one paragraph for the reasons discussed with respect to § 26.165(b).

The final rule, with respect to the proposed rule, includes a new requirement that the MRO must provide the donor with specific contact information and have the ability to verify the time the donor's call was received by the MRO's office if telephone notifications for retesting are the preferred method of the MRO's office. The NRC added this provision in response to a public comment received on the proposed rule that requested the addition to further protect donors' rights under the rule. The requirement is consistent with related requirements in the DOT's drug and alcohol testing procedures and, therefore, meets Goal 1 of the this rulemaking to enhance the consistency of Part 26 with the related regulations of other Federal agencies.

In § 26.165(b)(2) of the final rule, the NRC has modified the requirement in proposed § 26.165(a)(4) that a donor must inform the MRO in writing of his or her request to conduct testing of an aliquot of the single specimen or the specimen contained in Bottle B at a second

HHS-certified laboratory. This change is based on public comments received on the proposed rule which stated that requiring a donor to make a written request for additional specimen testing would be unduly restrictive given that other Federal agencies permit the donor to make these requests verbally. The NRC agrees that a donor should be provided with as much flexibility as possible, while ensuring the request is made in a secure and accurate manner. Therefore, the final rule permits the donor to make his or her request for additional testing verbally to the MRO or in writing. This change meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal drug and alcohol testing programs.

Section 26.165(b)(3) combines into one paragraph the requirements that were contained in the last sentences of proposed § 26.165(a)(4) and (b)(1) for the reasons discussed with respect to § 26.165(b). The final rule requires permission from the donor for testing Bottle B of a split specimen or retesting an aliquot of a single specimen and prohibits the MRO, NRC, or any other entity from requiring additional tests of a donor's specimen without his or her permission. These limitations are consistent with the principle established in § 26.31(d)(6) that affirms the donor's right to retain control over his or her specimen. Therefore, adding this provision meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

In § 26.165(b)(4) of the final rule, with respect to the proposed rule, the NRC has added a new provision that permits a donor to present to the MRO evidence supporting the inability of the donor to make a timely request for retesting of a single specimen or the testing of the Bottle B specimen after the 3–business day period permitted has elapsed. For example, a donor may have been severely ill when informed of a confirmed positive, adulterated, or substituted test result and was unable to contact the MRO to make the request because of hospitalization. On the basis of the information the donor presents, the MRO will make the sole determination

whether the circumstances described unavoidably prevented the donor from making a timely request. If the MRO makes this determination, he or she will direct a retest of an aliquot of a single specimen or testing of Bottle B of a split specimen by a second HHS-certified laboratory, as if a timely request was made. The NRC added this provision in response to public comments on the proposed rule, and has incorporated the related requirement in the DOT's procedures. The added provision protects donors' rights to fair and consistent testing procedures under the rule, consistent with Goal 7 of this rulemaking, and meets Goal 1 to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.165(b)(5) requires the MRO, in response to a donor's timely request for a retest of an aliquot of a single specimen or testing of Bottle B of a split specimen, to ensure that either the HHS-certified laboratory forwards an aliquot of a single specimen, or the HHS-certified laboratory or licensee testing facility forwards Bottle B of a split specimen, as appropriate, to a second HHS-certified laboratory that did not test the specimen in Bottle A. This paragraph amends the requirement in the fourth sentence of former Section 2.7(j) in Appendix A to Part 26, which required that the split specimen must be forwarded to another HHS-certified laboratory for testing on the same day of the donor request. The final rule requires the licensee testing facility or HHS-certified laboratory, as applicable, to forward Bottle B of a split specimen or the aliquot of a single specimen to a second laboratory as soon as reasonably practical and not more than 1 business day following the day of the donor's request. The NRC amended the former provision to respond to stakeholder comments during the public meetings discussed in Section I.D. The stakeholders indicated that implementing the "same-day" requirement for forwarding Bottle B in former Section 2.7(j) of Appendix A to Part 26 has often been difficult for a number of reasons. These reasons included communication delays among donors, MROs, the HHS-certified laboratory, and FFD program personnel,

particularly on weekends, holidays, and the time required to identify a second HHS-certified laboratory with the appropriate capability to test the specimen, depending on the nature of the positive test result. The change alleviates some types of logistical problems associated with weekends and holidays while continuing to provide the donor with timely test results. This change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. The final rule renumbers proposed § 26.165(a)(5) as § 26.165(b)(5) for the reasons discussed with respect to § 26.165(b).

Section 26.165(b)(6) retains the last sentence of former Section 2.7(j) in Appendix A to Part 26. This provision requires the second HHS-certified laboratory to provide quantitative test results from Bottle B to the MRO, who provides them to the donor. The rule adopts the simpler language from the related provision in the HHS Guidelines, consistent with Goal 6 of this rulemaking to improve clarity in the language of the rule. This provision also extends the former requirement to apply to communicating results from retesting an aliquot of a single specimen, consistent with the explicit permission the NRC has added for a donor to request retesting of a single specimen if the FFD program does not follow split specimen procedures. With respect to the proposed rule, § 26.165(b)(6) combines the redundant requirements in proposed § 26.165(a)(6) and (c)(4) for the reasons discussed with respect to § 26.165(b).

Section 26.165(c) [Retesting a specimen for drugs] amends former Section 2.7(i) in Appendix A to Part 26, which specified that retesting of a specimen is not subject to cutoff requirements. This paragraph updates and expands the former 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:

The NRC added § 26.165(c)(1) to require the second HHS-certified laboratory to use the laboratory's confirmatory test for the drug or drug metabolite for which the specimen tested positive at the first laboratory. The second HHS-certified laboratory will not conduct initial tests,

or tests for other drugs or drug metabolites, consistent with the related requirements in the HHS Guidelines. With respect to the proposed rule, for completeness, the final rule adds a reference to conducting confirmatory tests on specimens that the first laboratory confirmed to be positive and dilute as a result of the special analysis permitted in § 26.169(a)(2). In addition, in response to a public comment, the final rule eliminates the reference to the second laboratory's "standard" confirmatory drug test in the proposed provision because HHS-certified laboratories do not have "standard" confirmatory drug tests. The NRC made this change to enhance clarity in the language of the rule.

Section 26.165(c)(2) amends former Section 2.7(i) in Appendix A to Part 26, which specified that retesting of a specimen is not subject to cutoff requirements. The paragraph retains 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 adds permission to test the specimen at the assay's LOD. This addition ensures that the second laboratory's testing is as sensitive to the presence of the drug(s) or drug metabolite(s) as is scientifically and legally defensible.

The NRC has added § 26.165(c)(3) to require the second laboratory, if retesting fails to confirm the presence of the drug(s) or drug metabolite(s) identified by the first HHS-certified laboratory, to attempt to determine the reason why it could not reconfirm the drug test results from the first laboratory. The provision requires 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.

Section 26.165(c)(4) retains the requirement in the last sentence of former Section 2.7(j) in Appendix A to Part 26 that requires the second laboratory to report the test results of testing a split specimen to the MRO. The rule extends this requirement to reporting results from retesting an aliquot of a single specimen, consistent with the explicit permission the rule adds in

§ 26.165(b) for a donor to request retesting of a single specimen if the FFD program does not follow split specimen procedures. The requirement is consistent with the related requirements in the HHS Guidelines.

The NRC added § 26.165(d) [Retesting a specimen for adulterants] to incorporate related requirements in the HHS Guidelines for performing retests for adulterants at a second HHS-certified laboratory. The final rule limits retesting for adulterants to conducting confirmatory testing only for the adulterant(s) identified by the first laboratory. This limitation is consistent with limitations on retesting specimens for drugs and drug metabolites in the related requirements of the HHS Guidelines. With respect to the proposed rule, the final rule, when discussing confirmatory validity testing in § 26.165(d), replaces the phrase “appropriate confirmatory test” with “required confirmatory test” in response to a comment received on the proposed rule. The commenter noted that the confirmatory testing requirements in § 26.161(d) are “required” rather than “appropriate,” and the NRC concurs. The agency made this change to enhance the consistency of the final rule with the HHS Guidelines and improve clarity in the language of the rule.

The NRC added § 26.165(e) [Retesting a specimen for substitution] to incorporate related requirements in the HHS Guidelines for performing retests on substituted specimens at a second HHS-certified laboratory. The rule limits retesting for specimen substitution to conducting confirmatory testing only for creatinine and specific gravity. This limitation is consistent with limitations on retesting specimens for drugs and drug metabolites and the related requirements in the HHS Guidelines. With respect to the proposed rule, the final rule eliminates the second sentence of the proposed provision in response to a public comment that noted it was inconsistent with the related provision in the HHS Guidelines.

Section 26.165(f) [Management actions and sanctions] has been added to specify the management 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 NRC added this paragraph to establish the requirements for management actions and sanctions when an individual has had a confirmed positive, adulterated, or substituted test result and requests a retest of a single specimen or Bottle B of a split specimen. This section responds to stakeholder comments at the public meetings discussed in Section I.D. The stakeholders noted that the former rule did not address required management actions when an individual has had a confirmed positive test result and requests a retest of a single specimen or Bottle B of a split specimen. Therefore, the NRC added this section to establish such requirements.

The agency added § 26.165(f)(1) to address circumstances in which the MRO has confirmed a positive, adulterated, or substituted test result from the first HHS-certified laboratory that tested the specimen 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. This provision requires the licensee or other entity to take the same actions in response to the confirmed positive, adulterated, or substituted test result(s) from the first HHS-certified laboratory, as explained in § 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, § 26.165(f)(1) requires 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 reconfirm any positive, adulterated, or substituted test results from the first HHS-certified laboratory, the rule requires the licensee or other entity to impose the appropriate sanctions that are specified in subpart D for any positive, adulterated, or substituted results that were confirmed by the second laboratory. If the test results from the second laboratory do not reconfirm the positive, adulterated, or substituted test results from the first laboratory, the rule (1) prohibits the licensee or other entity from imposing any sanctions on the individual; (2) requires the licensee or other entity to eliminate any records

of the first confirmed positive, adulterated, or substituted results; and (3) requires 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 requirements 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 serving to protect the privacy rights of individuals who are subject to Part 26 and ensure that the individuals are afforded accurate and consistent testing.

The NRC added § 26.165(f)(2) 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, but are not limited to, an insufficient quantity of urine in the single specimen to permit retesting, either Bottle B or the aliquot of a single specimen is lost in transit to the second HHS-certified laboratory, or Bottle B has been misplaced. This provision requires the MRO to cancel the original test result, prohibits the licensee or other entity from imposing any sanctions on the donor, and requires the licensee or other entity to ensure that any records are expunged that could link the donor to the original positive, adulterated, or substituted, test result and the administrative action required under § 26.165(f)(1). The final rule, with respect to the proposed rule, adds the requirement that the MRO must direct the licensee or other entity to collect a second specimen under direct observation as soon as reasonably practical. The paragraph requires a second collection as soon as reasonably practical because other provisions of the regulation (see Subpart C) require negative test results in order for the licensee or other entity to grant or maintain the donor's authorization. The NRC made this change in response to public comments received on the proposed rule and to increase the consistency of Part 26 with the

related requirements in the HHS Guidelines.

The last sentence of § 26.165(f)(2) requires the licensee or other entity to impose the appropriate sanctions, as specified in Subpart D, if the results of testing the specimen from a second collection are positive, adulterated, or substituted and confirmed by the MRO to be an FFD policy violation. However, the rule prohibits 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 § 26.165(f) are generally consistent with the related requirements in the HHS Guidelines. The differences from the HHS Guidelines' requirements in the rule are 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 rule.

Section 26.167 Quality assurance and quality control.

Section 26.167 updates former Section 2.8 in Appendix A to Part 26 [Quality assurance and quality control], which established quality assurance and quality control requirements for drug testing at HHS-certified laboratories. This section provides more detailed requirements for the quality assurance and quality control programs of HHS-certified laboratories to improve consistency with related provisions in the HHS Guidelines, and adds new requirements for validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i).

Section 26.167(a) [Quality assurance program] amends and combines former Section 2.8(a) and the last two sentences of Section 2.8(d) in Appendix A to Part 26, which required HHS-certified laboratories and licensee testing facilities to have quality assurance programs. For increased clarity in the language of the rule, the rule replaces the term "specimen acquisition" with the term "specimen accessioning" in the first sentence of former

Section 2.8(a), which is the more accurate term. The rule also adds a requirement for the quality assurance program to encompass the certification of calibrators and controls to ensure that calibrators and controls are accurate. This requirement is consistent with the related provision in the HHS Guidelines.

In addition, the rule moves to § 26.167(a) and amends the requirements in the last two sentences of former Section 2.8(d) in Appendix A to Part 26, which required 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 rule updates these requirements for consistency with the HHS Guidelines and requires 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. The NRC relocated the updated requirements to § 26.167(a) for organizational clarity because they are aspects of the laboratory's quality assurance program.

The NRC has moved the requirements in former Section 2.8(a) in Appendix A to Part 26 that applied to licensee testing facilities to § 26.137(a) [Quality assurance program] in Subpart F [Licensee Testing Facilities]. Section § 26.167(a) retains the second sentence of former Section 2.8(a). The NRC also relocated the quality control requirements for initial tests at licensee testing facilities in former Section 2.8(b) in Appendix A to Part 26 to § 26.137 in Subpart F. The NRC made these changes for organizational clarity in the rule.

Section 26.167(b) [Calibrators and controls required] retains the portions of former Section 2.8(c) and (d) in Appendix A to Part 26 that required HHS-certified laboratories to use appropriate calibrators and controls for initial and confirmatory drug testing. The rule adds 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 rule, as discussed with respect to § 26.31(d)(3)(i). The NRC has added more detailed requirements for calibrators and controls to this section than were contained in the former section for consistency with the HHS Guidelines. The final rule presents these requirements in separate paragraphs that address each type of test to be performed by the HHS-certified laboratory for organizational clarity.

The NRC added § 26.167(c) [Quality control requirements for performing initial and confirmatory validity tests] 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 paragraph incorporate the related provisions of the HHS Guidelines.

The final rule adds § 26.167(c)(1) [Requirements for performing creatinine tests] to require HHS-certified laboratories to measure creatinine concentration to 1 decimal place on initial and confirmatory creatinine tests and to establish requirements for the quality control samples to be used in initial and confirmatory tests for creatinine concentration.

Section 26.167(c)(2) [Requirements for performing specific gravity tests] establishes the required characteristics of the refractometers that HHS-certified laboratories must use 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.

Section 26.167(c)(3) [Requirements for performing pH tests] establishes quality control requirements for performing initial and confirmatory pH tests. Section 26.167(c)(3)(ii) through (c)(3)(vi) specifies the required calibrators and controls for pH testing, based on the type of testing instrument used and whether the laboratory has performed a pH validity screening test. In response to a public comment on the proposed rule, the NRC relocated the requirements for calibrators and controls for an initial colorimetric pH test from § 26.167(c)(3)(ii) in the proposed rule to § 26.167(c)(3)(vi) in the final rule. The agency made this change to increase

consistency between the organization of Part 26 and the organization of the related requirements in the HHS Guidelines.

The NRC has added three additional paragraphs related to quality control of initial and confirmatory validity testing: § 26.167(c)(4) [Requirements for performing oxidizing adulterant tests], § 26.167(c)(5) [Requirements for performing nitrite tests], and § 26.167(c)(6) [Requirements for performing "other" adulterant tests]. These paragraphs establish quality control requirements for performing initial and confirmatory tests for oxidizing adulterants, among which nitrites are one example, and for "other" adulterants. The added paragraphs are consistent with the related requirements in the HHS Guidelines. With respect to the proposed rule, the agency made minor editorial changes to these provisions in response to public comments to improve the clarity of the requirements. For example, the NRC implemented one commenter's suggestion to add cross-references in § 26.167(c)(4)(i) and (c)(4)(ii) to the specific provisions in § 26.161 that establish the cutoff criteria for oxidizing adulterants to clarify the adulterant concentrations that calibrators must contain.

Section 26.167(d) [Quality control requirements for initial drug tests] amends and combines portions of former Sections 2.7(d) and (e)(1), and 2.8(c) in Appendix A to Part 26. The former sections established quality control requirements for performing initial tests for drugs and drug metabolites at HHS-certified laboratories. For organizational clarity, the final rule groups together these related requirements that were dispersed throughout the former rule. In addition, the NRC has amended a number of the former requirements, as follows:

Section 26.167(d)(1) updates the first sentence of former Section 2.7(e)(1) in Appendix A to Part 26 but retains the intent of the former provision as it applies to HHS-certified laboratories. This section requires laboratories to use only immunoassay tests that meet the requirements of the Food and Drug Administration for commercial distribution. The requirements in the former paragraph related to initial drug testing at licensee testing facilities

have been moved to § 26.137(e)(1) of Subpart F [Licensee Testing Facilities] to improve organizational clarity in the rule.

Section 26.167(d)(2) permits HHS-certified laboratories to conduct multiple tests of a single specimen for the same drug or drug class. The final rule, with respect to the proposed rule, includes an example to clarify this section in response to a public comment. The requirements and example in this paragraph are consistent with a similar provision in the HHS Guidelines.

Section 26.167(d)(3)(i)-(d)(3)(v) updates former Section 2.8(c) in Appendix A to Part 26. The former section required HHS-certified laboratories to include quality control samples in each analytical run of specimens for initial drug testing. Section 26.167(d)(3)(i)-(d)(3)(v) specifies the number and characteristics of the quality control samples to be included in each analytical run of specimens. With respect to the proposed rule, the final rule contains minor language clarifications. These requirements are identical to those contained in § 26.137(e)(6) and (e)(7) for initial drug tests at licensee testing facilities and have been added for consistency with the related provisions in the HHS Guidelines.

In addition, in response to a public comment on the organization of this section, the final rule, with respect to the proposed rule, moves proposed § 26.167(d)(3)(v) to § 26.167(d)(4) to improve organizational clarity. Section § 26.167(d)(4) requires that 10 percent of the specimens in each analytical run must be quality control samples.

Proposed § 26.167(e) [Quality control requirements for performing confirmatory drug tests] updates and combines portions of former Sections 2.7(f)(2) and 2.8(d) in Appendix A to Part 26. The former sections addressed quality control requirements for performing confirmatory drug tests. In general, the changes the NRC has made to the former requirements are made for organizational clarity in the final rule and to incorporate the related provisions in the HHS Guidelines.

Section 26.167(e)(1) amends former Section 2.7(f)(2) in Appendix A to Part 26. The former provision required that confirmatory drug tests must be performed using gas chromatography/mass spectrometry (GC/MS). The final rule permits HHS-certified laboratories to use other techniques for confirmatory drug testing that the HHS Guidelines approve for use in Federal workplace drug testing programs.

The NRC added § 26.167(e)(2) to update Section 2.8(d) in Appendix A to Part 26 by establishing a requirement for the percentage of quality control samples that HHS-certified laboratories must include in each analytical run for confirmatory testing. The former rule did not specify a percentage. The NRC added this requirement for consistency with the HHS Guidelines. With respect to the proposed rule, the final rule separates the first and second sentences of the proposed provision into separate paragraphs and renumbers the second sentence of proposed § 26.167(e)(2) as § 26.167(e)(3) for organizational clarity, in response to a public comment.

Section 26.167(e)(3)(i) through (e)(3)(iv) amends the requirements for quality control samples in former Section 2.8(d) in Appendix A to Part 26. The final rule, with respect to the proposed rule, makes minor language clarifications in this paragraph. Section 26.167(e)(3)(i) and (e)(3)(ii) retains the former requirements for laboratories to include blank samples and samples that contain known standards in each analytical run. The requirements 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 paragraph provides more detailed requirements for "positive controls with the drug or metabolite at or near the threshold" than in former Section 2.8(d)(1) in Appendix A to Part 26. The rule requires, in § 26.167(e)(3)(iii), at least one control fortified with a drug or drug metabolite targeted at 25 percent above the cutoff and, in § 26.167(e)(3)(iv), at least one calibrator or control that is targeted at or below 40 percent of the cutoff.

The NRC moved the requirements in proposed § 26.167(f) [Blind performance testing] to a new section in the final rule, § 26.168 [Blind performance testing]. The agency made this change because licensees and other entities, rather than HHS-certified laboratories, are primarily responsible for implementing these requirements. Therefore, presenting requirements for licensees' and other entities' blind performance testing of HHS-certified laboratories in a separate section makes them easier to locate in the final rule and meets Goal 6 to improve clarity in the organization of the rule.

With respect to the proposed rule, the final rule renumbers proposed § 26.167(g) [Errors in testing] as § 26.167(f). This section amends former Section 2.8(e)(4) through (e)(6) in Appendix A to Part 26, and imposes requirements on licensees, other entities, and HHS-certified laboratories related to unsatisfactory performance, including false positive and false negative test results from the HHS-certified laboratory. This paragraph requires 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 rule no longer requires the licensee to perform the investigation, but rather to "ensure" that the laboratory completes an investigation. The NRC made this change 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 HHS-certified laboratories. The agency has moved the requirements for reporting and documentation of the investigation, which formerly appeared in Section 2.8(e)(4) in Appendix A to Part 26, to §§ 26.715(b)(8) and 26.719(c) in Subpart N [Recordkeeping and Reporting Requirements] of the final rule for organizational clarity.

Section 26.167(f)(1) explicitly states the requirements that were implied in former 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 rule expands these requirements to include the licensee or other entity, as well as

the HHS-certified laboratory, depending on the causes identified and the extent to which the causes are within each entity's control. The NRC revised the former requirement to recognize that some testing errors are not attributable to the HHS-certified laboratory.

Section 26.167(f)(2) amends former Section 2.8(e)(5) in Appendix A to Part 26. This provision required the licensee to notify the NRC if a false positive error occurred on a blind performance test sample and the error was determined to be technical or methodological. The final rule requires 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 this section. The rule continues 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 rule also deletes reference to administrative errors, which appeared in former Section 2.8(e)(5), so that any type of errors falls under the requirements of the paragraph. The NRC moved the reporting requirement in former Section 2.8(e)(5) to § 26.719(c)(2) in Subpart N [Recordkeeping and Reporting Requirements] for organizational clarity.

Section 26.167(f)(3) amends former Section 2.8(e)(6) in Appendix A to Part 26. This section addressed false positive errors resulting from methodological errors by the laboratory. The rule incorporates reference to validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as previously discussed with respect to § 26.31(d)(3)(i). The rule deletes the last sentence of the former paragraph because it addressed 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 paragraph retains the other provisions of former Section 2.8(e)(6), but adopts the simpler language of the related provision in the HHS Guidelines for increased clarity in the language of the rule. With respect to the proposed rule, the final rule replaces the term “certifying scientist” in the third sentence of the proposed

provision with the accurate term “responsible person” in response to a public comment which noted the use of the incorrect term in the proposed rule.

Section 26.167(g) [Accuracy] retains former Section 2.7(o)(3)(i) in Appendix A to Part 26 with minor editorial revisions. The agency relocated the former paragraph to § 26.167(g) because it relates to quality control of the HHS-certified laboratory's drug testing processes. The NRC made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.167(h) [Calibrators and controls] updates former 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 final rule updates former 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 requirements in this paragraph incorporate the related requirements in the HHS Guidelines and meet Goal 1 of this rulemaking 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 former Section 2.7(o)(2) have been retained without change.

Section 26.168 Blind performance testing.

Section 26.168 updates and expands former Section 2.8(e) in Appendix A to Part 26 [Licensee blind performance test procedures]. The former paragraph established requirements for licensees and other entities to conduct blind performance testing of HHS-certified laboratories. With respect to the proposed rule, the final rule has moved the requirements in proposed § 26.167(f) to this new section because presenting them in a separate section makes

them easier to locate in the final rule. The final rule also provides more detailed requirements for the formulation of blind performance test samples that licensees and other entities use to obtain HHS-certified laboratory performance data and revises the number, composition, and percentages of blind samples that licensees and other entities must submit to the HHS-certified laboratories. The NRC made these changes in response to detailed public comments that addressed these issues.

The NRC added § 26.168(a) to require licensees and other entities to submit blind performance test samples to the HHS-certified laboratories with whom they contract for drug testing services. To improve clarity in the language of the rule, the NRC added this provision to make explicit the same requirement that was implied in former Section 2.8(e) of Appendix A to Part 26.

Section 26.168(a)(1) amends the portion of former Section 2.8(e)(2) in Appendix A to Part 26 that established 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 final rule decreases the percentage of blind performance test samples that licensees and other entities must submit to the HHS-certified laboratory during the initial 90-day period of any contract (not including rewritten or renewed contracts). Specifically, the rule reduces 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 former rule. This decrease in the blind performance testing rate increases the consistency of Part 26 with related provisions in the HHS Guidelines. In addition, since the NRC published the former rule, the number and size of Federal agencies who conduct drug testing has substantially increased. These agencies are also required to submit blind performance test samples under the HHS Guidelines. As a result, especially with respect to the issue of correctly identifying negative

specimens, the burden on Part 26 programs to conduct performance tests of the HHS-certified laboratories can be reduced without affecting the likelihood that errors in testing will be detected.

The regulation also adds a requirement for licensees and other entities to submit a minimum of 30 blind performance test samples in the initial 90-day period. The agency has established this minimum 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 initial 90-day period could be less than one blind performance test sample. Establishing a minimum number of samples will provide assurance that the HHS-certified laboratories used by these Part 26 programs are providing accurate test results.

Section 26.168(a)(2) amends the portion of former Section 2.8(e)(2) in Appendix A to Part 26 that addressed ongoing blind performance testing after the first 90 days of an initial contract with an HHS-certified laboratory. The rule decreases 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 former rule to one percent, or a total of 10 samples, whichever is greater. The rule also decreases the maximum number of samples to be submitted per quarter from 250 to 100 samples. The rationale for these changes is the same as discussed with respect to § 26.168(a)(1).

The NRC added § 26.168(a)(3) to require licensees and other entities to submit blind performance test samples to the HHS-certified laboratory at a frequency that is similar to the frequency for other specimens. This change enhances the consistency of Part 26 with the HHS Guidelines.

Section 26.168(b) amends and expands former Section 2.8(e)(3) in Appendix A to Part 26, which required 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). With respect to the proposed rule, the NRC has substantially changed the requirements in proposed § 26.167(f)(3) in response to extensive comments on the proposed blind performance test sample provisions. In the final rule, § 26.168(b) now requires that approximately 60 percent of all blind performance test samples that licensees and other entities send to the HHS-certified laboratory must be positive for one or more of the drugs for which the licensee or other entity tests, and that all drugs for which the licensee or other entity tests must be submitted to the HHS certified laboratory at least once a quarter except as indicated in §26.168(b)(1) and (2). The requirement that approximately 60 percent of all blind samples submitted to HHS-certified laboratories must be positive for one or more drugs per sample will ensure that all licensees, including those who will only send the minimum number of blind samples required under this rule, will submit several samples for each drug being tested. This change will permit licensees and other entities to better monitor and make more informed decisions regarding their HHS-laboratories' performance. Under the previous "80% negative" rule, licensees who submitted only the 40 minimum blind samples required would nominally receive two results per year on three drugs (which were chosen by the licensee or other entity). This requirement provided licensees with scant information to determine independently, as required by rule, whether the HHS-certified laboratory was meeting the licensee or other entity contract provisions with the HHS-certified laboratory. Under the revised section, assuming a reasonable distribution, even those licensees and other entities who submit only the minimum 40 required blind samples a year will receive results from marijuana blind performance test samples at least 8 times a year, from cocaine text samples at least 7 times a year, from amphetamines and opiate test samples at least 3 times a year, and from PCP test samples at least twice a year. The NRC’s increased emphasis on testing for marijuana and cocaine and the reduction in testing for PCP in § 26.168(b)(1) and (2) reflect the fact that among all FFD

programs, marijuana and cocaine have resulted in the largest number of confirmed positive drug tests and PCP the least number of confirmed positive drug tests, as reported in the NRC's "Summary of FFD Performance Reports", from 1990 through 2005. Therefore, the NRC has made these changes to meet Goal 3 of this rulemaking to enhance the effectiveness and efficiency of the rule.

Section 26.168(c) limits the submission of positive blind performance test samples to the HHS-certified laboratory to samples containing only those drugs for which the licensee or other entity tests and requires that the blind samples sent to HHS-certified laboratories must be formulated according to the requirements established in § 26.168(g)(2). This provision updates former Section 2.8(e)(3) in Appendix A to Part 26, which also limited performance testing to only those drugs included in the licensee's panel. With respect to the proposed rule, the final rule replaces the proposed requirement for positive samples to be spiked to between 60–80 percent of the initial cutoff levels used by the licensee or other entity with a cross-reference to the more detailed requirements for positive blind performance test samples in § 26.168(g)(2), as discussed with respect to that section.

The NRC has added § 26.168(d) to require licensees and other entities to submit approximately 10 percent of all blind performance test samples as false negative challenge samples to the HHS-certified laboratory according to the requirements established in § 26.168(g)(3). The NRC has added this provision in response to public comments on proposed § 26.167(f) that blind samples containing drugs or drug metabolites at a concentration 20 percent above the cutoff levels would frequently yield false negative test results and, therefore, unfairly challenge HHS-certified laboratories. False negatives occur when drug levels that are positive but close to the initial drug test cutoff level may actually be reported as negative. Assuming that an initial negative drug test has an error rate of one percent (one percent false negatives) and all HHS-certified laboratories perform equally, then over time, for

every 100 people who have recently used drugs and been tested by licensees and other entities, one person will not be identified as having a positive test result for one or more drugs on the basis of the initial test alone. Recent research [Cone et. al., 2003)] strongly suggests that the issue of false negatives may be significantly greater than previously understood. The NRC recognizes that false negatives will occur within its drug testing guidelines, but intends to minimize them as much as is reasonably possible within scientific constraints and practical limitations of resources. Therefore, the NRC has established the requirements for the characteristics of false negative challenge samples under the final rule to present a fair test to HHS-certified laboratories because they are targeted at specimens clearly above the range of laboratory controls yet below the standard cutoff levels.

Section 26.168(e) requires licensees and other entities to submit approximately 20 percent of all blind samples as adulterated, diluted, or substituted and formulated according to the requirements established in § 26.168(g)(4)-(g)(6). The NRC added this provision 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). This performance testing is necessary to challenge the accuracy of the HHS-certified laboratories' specimen validity testing. With respect to the proposed rule at proposed § 26.167(f)(3), the final rule increases the proportion of blind samples that licensees and other entities must submit to challenge the laboratories' specimen validity testing. The NRC made this change in response to public comments on the proposed rule and the NRC's concern that validity test results are accurate. The requirements elaborated in this section protect public health and safety and the common defense and security by increasing the effectiveness of FFD programs (Goal 3 of this rulemaking) in ensuring that an individual whose fitness for duty is questionable does not perform duties or have the types of access that require the individual to be subject to this part.

The final rule substantially decreases the percentage of negative blind performance test

samples that licensees were required to submit to HHS-certified laboratories in former Section 2.8(e)(3) of Appendix A, as retained in proposed § 26.168(f). The former and proposed provision required 80 percent of blind samples to be negative. The final rule revises this percentage to 10 percent. The NRC made this change in response to public comments on the proposed rule and because the NRC believes that carryover effects (i.e., a positive sample contaminates a negative sample because of improper laboratory equipment cleaning), while a concern during the early years of drug testing, are not an issue in current HHS-certified laboratories based on current specimen testing practices. The agency also believes that it is more appropriate to challenge the drug and validity testing capabilities of HHS-certified laboratories and therefore, is increasing the percentage of positive, adulterated, substituted, dilute, and invalid specimens submitted as blind performance test samples in each quarter of testing. With regard to the issue of correctly identifying negative specimens (i.e., ensuring that laboratories do not report false positive test results), the NRC is confidant that the 10 percent negative sample requirement in the final rule will provide adequate oversight regarding false positive test results due to carryover and other related issues. Another reason that the NRC is decreasing the required percentage of negative samples in the final rule is that the number and size of Federal agencies who conduct drug testing has substantially increased since Part 26 was first promulgated. Also, these agencies are required to submit negative blind performance test samples at a rate of 80 percent under the HHS Guidelines. Therefore, the previous need for Part 26 programs to so extensively challenge the HHS-certified laboratories' false positive rates is reduced.

The NRC has added formulation standards for the blind performance test samples that licensees and other entities must use in § 26.168(g). The final rule revises proposed § 26.167(f)(5)(i) in response to detailed public comments on the scientific and technical suitability of the proposed standards in achieving the NRC's objective of ensuring that the

performance testing required under this rule ensures that test results from HHS-certified laboratories are accurate.

The agency added § 26.168(g)(1) to require that negative blind performance test samples may not contain a measurable amount of a target drug or analyte, and must be confirmed by immunoassay and confirmatory testing. Section 26.168(g)(2) requires that positive blind performance test samples must contain drug or analyte concentrations between 150 and 200 percent of the initial cutoff levels and be certified by immunoassay and confirmatory testing to contain one or more drug(s) or drug metabolites. Section 26.168(g)(3) requires that false negative challenge samples must contain target drug or analyte concentrations between 130 and 155 percent of the initial cutoff values. Section 26.168(g)(4) requires that an adulterated blind performance test sample must have a pH of less than or equal to 2, or greater than or equal to 12, or nitrite or other oxidant concentration equal to or greater than 500 mcg/mL) using either a nitrite colorimetric test or a general oxidant colorimetric test. Section 26.168(g)(5) requires that a dilute blind performance test sample must contain a creatinine concentration that is equal to or great than 5 mg/dL but less than 20 mg/dL, and the specific gravity must be greater than 1.0010 but less than 1.0030. Section 26.168(g)(6) requires that a substituted blind performance test sample must contain less than 2 mg/dL of creatinine and the specific gravity must be less than or equal to 1.0010, or equal to or greater than 1.0200.

The NRC has made these changes in § 26.168(b)-(g) to increase the ability of licensees and other entities to independently monitor the ability of their HHS-certified laboratories to consistently identify positive, adulterated, dilute, and substituted specimens and hold false negatives to a minimum. The NRC recognizes that these issues are routinely scrutinized and evaluated by the HHS Laboratory Certification Program (LCP), but is mindful that the LCP challenges are not blind to the HHS-certified laboratories. Because of its over-arching interest in making the Part 26 drug testing program as rigorous as possible, as evidenced by the detail

of Subparts F and G, the NRC believes that a more aggressive licensee and other entity blind challenge to the HHS-certified laboratories in these area adds an important independent dimension to ensuring licensee and other entity confidence in the overall drug testing program.

Section 26.168(h) has been added to establish additional detailed requirements for the blind performance test samples that licensees and other entities must submit to the HHS-certified laboratories and to ensure the consistency and effectiveness of the blind performance testing process. Section 26.168(h)(1) requires the supplier of the blind samples to certify that all blind specimen batches are confirmed by an HHS-certified laboratory prior to being put into service and to remove blind specimen batches from service after they have been open for 6 months. Section 26.168(h)(2) requires the supplier to provide an expiration date for each sample. Section 26.168(h)(3) requires the supplier to monitor each open batch on a bi-monthly (i.e., every two months) basis to ensure that the remaining batch does not fall below the criteria in this section. These requirements are based on related provisions in the HHS Guidelines and DOT's procedures for drug and alcohol testing. The NRC added these requirements in response to a public comment on the proposed rule requesting the NRC to clarify the requirements in proposed § 26.167(f)(5).

The NRC added § 26.168(i) to provide specific requirements for ensuring that blind performance test samples are indistinguishable to laboratory personnel from a donor's specimen in response to a public comment on proposed § 26.167(f)(5). These requirements are based on the related DOT procedures.

Section 26.168(i)(1) requires the licensee or other entity to ship blind performance test samples to the HHS-certified laboratory in the same way donors' specimens are sent to the laboratory. This provision provides greater assurance than the former rule that personnel at the HHS-certified laboratories will not be aware that the specimen they are handling is a blind performance test sample. The NRC added this provision to increase the effectiveness of blind

performance testing under the rule.

Section 26.168(i)(2) specifies the information that must be entered on the custody-and-control form accompanying the blind performance test sample. This information is necessary to ensure that the MRO is aware that the specimen is a blind performance test sample.

Section 26.168(i)(3) requires licensees and other entities to submit split samples where applicable. This provision is necessary to ensure that the FFD program submits blind performance tests samples that appear to be normal specimens that the laboratory may received from a donor.

Section 26.169 Reporting results.

This section contains requirements for HHS-certified laboratories' reporting of test results to the licensee's or other entity's MRO. The final rule in § 26.169 updates former Section 2.7(g) in Appendix A to Part 26. The rule updates the former requirements for consistency with the HHS Guidelines. In addition, the rule adds requirements for reporting the results of validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). With respect to the proposed rule, the NRC has made several organizational changes to improve clarity by presenting the provisions in the order that is more consistent with the order in which HHS-certified laboratories, licensees, and other entities will implement them, consistent with Goal 6 of this rulemaking.

Section 26.169(a) amends former Section 2.7(g)(1) in Appendix A to Part 26, which established 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 NRC has retained the requirement for the laboratory to report results to the MRO within 5 business days of receiving the specimen at the laboratory. Under the final rule, the HHS-certified laboratory's "certifying scientist," rather than the laboratory's "responsible individual," certifies the test results. This

change has been made for consistency with the updated term used to refer to this individual, as discussed with respect to § 26.155(b). The rule adds 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 § 26.31(d)(3)(i). The final rule deletes the former 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 former rule was based on 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 former rule.

Section 26.169(b) amends portions of former Section 2.7(f)(2) in Appendix A to Part 26 by eliminating 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. If the FFD program specifies cutoff levels that are more stringent than those specified in this part, the final rule requires the laboratory only to conduct testing using those more stringent cutoff levels, and only to report results from those tests to the MRO. The NRC made this change for the reasons discussed with respect to § 26.31(d)(1)(i)(D). This provision was § 26.169(c) in the proposed rule.

Section 26.169(c) (§ 26.169(b) in the proposed rule) establishes requirements for the laboratory's reporting of validity test results. This provision amends former Section 2.7(g)(2) in Appendix A to Part 26, which established requirements for the manner in which HHS-certified laboratories and licensee testing facilities must report test results to licensee management. The NRC has moved the requirements in the former paragraph that are related to reporting test results from the licensee testing facility to § 26.139(a) of Subpart F [Licensee Testing Facilities]

for organizational clarity. The final rule deletes the former reference to “special processing” and replaces it with reference to validity test results, consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). In addition, the final rule makes minor changes in terminology, such as referring to a “drug or drug metabolite,” rather than a “substance,” for clarity in the rule language.

The NRC has renumbered proposed § 26.169(e) as § 26.169(c)(1) in the final rule. The NRC added this provision to require the HHS-certified laboratory to report all test results for a single specimen, if the laboratory obtains more than one positive, adulterated, substituted, or invalid test result from testing of the specimen. The regulation requires the laboratory to report any positive test results, as well as any adulterated, substituted, or invalid validity test results from the same specimen. This change is necessary because sanctions for the different test results differ under § 26.75. Reporting multiple test results for a single specimen is consistent with related requirements in the HHS Guidelines.

Section 26.169(c)(2) updates former Section 2.7(g)(3) in Appendix A to Part 26, which permitted the MRO routinely to obtain quantitative test results from the HHS-certified laboratory. This paragraph incorporates the first two sentences of proposed § 26.169(d). Specifically, the final rule revises the first sentence of former Section 2.7(g)(3) by stating that the HHS-certified laboratory shall provide quantitative test results for a positive confirmatory drug test result to the MRO on request. The paragraph clarifies the former 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 changes to this paragraph are consistent with the related provisions in the HHS Guidelines. The final rule also moves the requirement that was contained in proposed § 26.169(g) to this paragraph for organizational clarity. Therefore, this provision of the final rule requires the HHS-certified laboratory to routinely report to the MRO, whether requested or not, quantitative values for confirmatory opiate test results for morphine or codeine that are equal to

or greater than 15,000 ng/mL. The rule adds this requirement for consistency with the related provision in the HHS Guidelines and because the MRO is not required to perform an assessment for clinical signs of opiate abuse in this instance, as discussed with respect to § 26.185(j)(1). The reference to test results from blood specimens in former Section 2.7(g)(3) in Appendix A to Part 26 has been deleted for the reasons discussed with respect to § 26.83(a).

In response to public comments on the proposed rule, the NRC has added § 26.169(c)(3) to require the HHS-certified laboratory to report to the MRO numerical values supporting an adulterated or substituted test result. The final rule also adds instructions for the laboratory's report to the MRO if a specimen's numerical values for creatinine are below the LOD. The NRC added this provision for consistency with the HHS Guidelines.

Section 26.169(c)(4) requires the HHS-certified laboratory to contact the MRO after the HHS-certified laboratory has determined that a specimen has an invalid result, but before reporting out the test result, to determine whether testing by a second HHS-certified laboratory would be useful. The rule permits the laboratory's contact with the MRO to occur using electronic means, such as telephone, fax, and email. If no further testing is necessary, the final rule requires the laboratory to report the invalid result to the MRO. These reporting requirements have been added for consistency with the related provisions in the HHS Guidelines. This provision retains the portions of proposed § 26.169(d) that pertained to reporting invalid test results but the final rule presents them in a separate paragraph to improve organizational clarity.

Section 26.169(c)(5) establishes requirements for the HHS-certified laboratory in reporting drug, metabolite, or adulterant concentrations that exceed normal testing ranges. This provision updates the last sentence of former Section 2.7(f)(2) in Appendix A to Part 26 for consistency with the HHS Guidelines. This provision appeared in the proposed rule as the third sentence of proposed § 26.169(d).

Section 26.169(d) retains the portion of former Section 2.7(g)(3) in Appendix to Part 26 that prohibited the MRO from disclosing quantitative results to a licensee or other entity and extends it to MRO staff for clarity in the language of the rule. This provision requires the MRO to only report whether the specimen was positive (and for which analyte), adulterated, substituted, dilute, invalid, or negative, except as permitted under § 26.37(b). This provision appeared as the fourth and fifth sentences of proposed § 26.169(f).

Section 26.169(e), which was § 26.169(h) in the proposed rule, amends former Section 2.7(g)(4) in Appendix A to Part 26, which established requirements for the electronic transmission of test results from the HHS-certified laboratory to the MRO. Specifically, the rule clarifies 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 former requirement. This change responds 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. This revision accurately characterizes these relationships without changing the intent of the former provision.

Section 26.169(f) updates former Section 2.7(g)(5) in Appendix A to Part 26, which established requirements for transmitting chain-of-custody documentation with test results to the MRO. The rule permits HHS-certified 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 positive, adulterated, substituted, or invalid test results, the rule requires the laboratory to transmit a legible image or copy of the completed custody-and-control form to the MRO. The change has been made for consistency with the related provision in the HHS Guidelines. This provision contains the requirements in § 26.169(i) of the proposed rule.

Section 26.169(g) further amends former Section 2.7(g)(5) in Appendix A to Part 26. The paragraph continues to require that the HHS-certified laboratory must retain the original custody-and-control form for any positive, adulterated, substituted, or invalid specimens. However, the paragraph assigns 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 change has been made for consistency with the updated terminology used to refer to this individual in the HHS Guidelines, as discussed with respect to § 26.155(b). This provision was § 26.169(j) in the proposed rule.

Section 26.169(h) combines and amends former Section 2.7(g)(6) and (g)(7) in Appendix A to Part 26, which required the laboratory to submit a monthly statistical summary of drug test results to the licensee or other entity. The rule reduces 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 requirement for annual reporting makes 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 is required under § 26.717, for the reasons discussed with respect to that section. The rule also deletes the existing reference to blood specimens because the option for donors to request blood testing for alcohol has been eliminated from the rule, as discussed with respect to § 26.83(a). The rule also deletes 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 § 26.169(b). The rule adds 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-AM test results. (The rule includes testing for 6-AM, because the presence of 6-AM in a specimen uniquely identifies heroin use.)

In addition, the rule adds requirements to report the results of validity testing. The NRC has made these changes to conform to other changes in the rule, as discussed with respect to § 26.717(b)(2), 26.185(j)(1), and 26.31(d)(3)(i). With respect to the proposed rule, the NRC has added requirements for the laboratory to report whether a specimen that has been reported as positive and dilute was subject to the special analyses permitted under § 26.163(a)(2) and the number of specimens reported as rejected for testing. The NRC added these reporting requirements in response to public comment noting that the NRC will require this information to maintain adequate oversight of FFD programs and for consistency with related provisions in the HHS Guidelines. This requirement appeared as proposed § 26.169(k) in the proposed rule.

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

Throughout this subpart, the final rule makes minor clarifications to the proposed rule because of public comment, to accommodate conforming changes, and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. For example, the final rule eliminates the term “non-negative,” which was used in proposed Subpart H in many places and replaces it with the terms “positive, adulterated, substituted, dilute, or invalid,” as appropriate, for the reasons discussed with respect to § 26.5 [Definitions]. Also, in § 26.185, the final rule adds the term "confirmatory" when referring to test results that have been reported to the MRO by the HHS-certified laboratory and deletes the ambiguous term "referral" when referring to a physician. The final rule also uses "business days" instead of only "days" to be consistent with other provisions in the rule.

The final rule also makes more substantive changes to the proposed rule in this subpart because of public comment or to improve clarity in the organization and language of the rule. The substantive changes in this subpart can be found in §§ 26.183(b), (d), (d)(1), and (d)(2)(iv); 26.185(g), (g)(2), (g)(5), (h)(1), and (i)(1); 26.187(a) and (f); and 26.189(a) and (c). These

changes are discussed in detail below. However, other than the changes mentioned above, the final rule adopts the provisions of this subpart as proposed, without change.

Section 26.181 Purpose.

Section 26.181 of the final rule describes the purpose of Subpart H, which is to establish requirements for MRO reviews of positive, adulterated, substituted, dilute or invalid confirmatory drug test results and for making determinations of fitness. This section provides an overview of the contents of the subpart, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.183 Medical review officer.

The NRC has added § 26.183 to the final rule to present requirements related to the qualifications, relationships, staff, and responsibilities of the MRO. Grouping these requirements together in a single section meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.183(a) [Qualifications] of the final rule combines and amends the requirements in former § 26.3 [Definitions] and Section 1.2 of Appendix A to Part 26, as well as portions of former Section 2.9(b) in Appendix A to Part 26. The provision reorganizes the former requirements to eliminate redundancies and group in one paragraph the related provisions in the former rule. These changes meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The provision amends portions of the former requirements related to MRO qualifications. It continues to provide that the MRO must be a licensed physician, but clarifies 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 provision adds 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 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 provision ensures that an MRO is able to perform his or her function appropriately under this part. In addition, the provision adds 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 requirement increases consistency in the performance of the MRO function among FFD programs because licensees and other entities are permitted to accept test results and the results of determinations of fitness conducted by other licensees and entities who are subject to the FFD rule. The 2-year implementation date provides MROs who are not currently certified with an opportunity to pass the required examination. With the exception of the first sentence of this provision that specifically relates to the MRO function under Part 26, these MRO qualification requirements are consistent with those of other Federal agencies.

Section 26.183(b) [Relationships] of the final rule establishes requirements related to the relationships that are permitted or prohibited between the MRO, the licensee or other entity, and HHS-certified laboratories. The first sentence of this provision retains the portion of the first sentence of former Section 2.9(b) in Appendix A to Part 26 that permitted the MRO to be an employee of a licensee or other entity, or a contractor. The NRC has added requirements 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 NRC has added this prohibition based upon the experiences of other Federal agencies and to be consistent with the related provision in the HHS Guidelines, consistent with Goal 1 of the rulemaking to update and enhance the

consistency of Part 26 with advances in other relevant Federal rules and guidelines.

With respect to the proposed rule, the final rule adds the last sentence of § 26.183(b) and paragraphs (b)(1) through (b)(6) to provide some examples of relationships between laboratories and MROs that create conflicts of interest. The NRC has included these examples in response to a public comment requesting more clarification regarding such conflict-of-interest relationships. The basis for these examples is 49 CFR Part 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs" (65 FR 41944; August 9, 2001). Adding these examples meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other Federal rules and guidelines and Goal 6 of the rulemaking to improve clarity in the rule language.

Section 26.183(c) [Responsibilities] of the final rule reorganizes and updates the requirements in former § 26.3 [Definitions], as well as former Sections 1.2, 2.4(j), 2.7(d), and 2.9(a) and (b) in Appendix A to Part 26 to specify the responsibilities of the MRO in Part 26 programs. This provision reorganizes the former provisions and combines them. In addition, the NRC has revised the terminology to be consistent with that used throughout the FFD rule. These changes meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.183(c) retains the requirement in former Section 2.9(a) in Appendix A to Part 26 for the MRO to review positive confirmatory drug test results from the HHS-certified laboratory. The provision also adds a requirement for the MRO to review adulterated, substituted, or invalid results from confirmatory validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). If a licensee's or other entity's FFD program elects to conduct the special analyses of dilute specimens permitted in § 26.163(a)(2), the MRO also is required to review those results. This provision also requires the MRO to identify evidence of subversion of the

testing process, identify issues or problems associated with the collection and testing of specimens, and work with FFD program management to ensure the overall effectiveness of the FFD program. The final rule adds 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 additional responsibilities strengthen the effectiveness of FFD programs by ensuring that the MRO's expertise is brought to bear in the management of FFD programs. This provision also increases 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 changes meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.183(c)(1) retains and updates the former definitions of the term "Medical Review Officer" contained in former § 26.3 and Sections 1.2 and 2.9(b) in Appendix A to Part 26. This provision continues to require the MRO to examine alternate medical explanations for any positive drug test results. It also adds a requirement to examine alternate medical explanations for adulterated, substituted, invalid, or, at the licensee's or other entity's discretion, dilute test results report by the HHS-certified laboratory. The provision also retains the former provision that the MRO may interview the donor and review the donor's medical history and any other relevant biomedical factors, and review all medical records that the donor may make available to the MRO. In addition to the responsible use of legally prescribed medication, this provision requires the MRO to consider a documented condition or disease state and the demonstrated physiology of the donor in determining whether a positive, adulterated, substituted, or invalid test result is an FFD policy violation. The provision requires the MRO to consider the latter factors because they may cause some adulterated, substituted,

invalid, or dilute validity test results. These changes are necessary for consistency with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). The changes also increase the consistency of Part 26 with advances in other relevant Federal rules and guidelines, which is Goal 1 of this rulemaking.

Section 26.183(c)(2) retains the meaning of the last sentence of former Section 2.9(b) in Appendix A to Part 26 , but adds minor editorial revisions for consistency with the terminology used throughout the rule. For example, the rule replaces the term “split samples” in the former rule with the term “split specimens.” The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.183(d) [MRO staff] to the final rule 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. This provision adds requirements related to MRO staff because these individuals have access to drug test results that are forwarded to an MRO from the HHS-certified laboratory, perform some administrative functions for MROs that permit them to view donors’ private medical information, and often have contact with donors. The NRC is not aware of any instances when 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, this provision adopts 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 requirement also ensures that information related to positive, adulterated, substituted, invalid, or dilute test results is not released to licensee or other entity management personnel unless the MRO has determined that a donor has violated the FFD

policy. These changes meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines and Goal 7 to protect the privacy and due process rights of individuals who are subject to Part 26.

With respect to the proposed rule, the final rule adds another sentence to § 26.183(d) to clarify that employees of a licensee or other entity who serve MRO staff functions may also perform other duties for the licensee or other entity and need not be under the direction of the MRO while performing those other duties. The final rule also clarifies § 26.183(d)(1) to reflect this intent and specify that individuals who serve MRO staff functions need only to be under the direction of the MRO while performing those functions. The NRC has added these changes to specify NRC's intent in response to a public comment that requested clarification on this issue.

The NRC has added § 26.183(d)(1) [Direction of MRO staff activities] to require an MRO to be directly responsible for the administrative, technical, and professional activities of individuals who perform MRO staff duties. As discussed with respect to § 26.5 [Definitions], directing means the exercise of control over a work activity by an individual who is directly involved in the execution of the activity and either makes technical decisions for that activity without subsequent technical review, or is ultimately responsible for the correct performance of that work activity. The NRC does not intend 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. Also, the definition of directing, specifically the phrase "directly involved in the execution of the work activity," does not require the MRO to be onsite when giving direction to individuals who are performing MRO staff functions. For example, the MRO must be directly involved in the work of on-site licensee MRO staff, even if that direct involvement occurs by telephone. Direction may also take place through using a variety of electronic communications.

However, this provision requires that the MRO's direction of staff must be meaningful.

Meaningful direction involves personal oversight of staff members' work; providing input to their performance evaluation; line authority over the staff for decisions, direction, and control; and regular contact and oversight concerning drug testing program matters. This provision also requires 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 provision requires that MROs must personally review a confirmed positive drug test result that is received from the HHS-certified laboratory, as well an adulterated, substituted, invalid, or dilute result. This requirement is consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i).

Section 26.183(d)(1)(i) requires that MRO staff duties must be independent from any other activity or interest of the licensee or other entity. The rule has added this requirement because, in 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 when the MRO and his or her staff are physically co-located, such as the inadvertent release of positive, adulterated, substituted, or invalid test results before the MRO has discussed the results with the donor. Therefore, the NRC believes that the requirement is necessary to protect the integrity of the MRO function and donors' privacy, consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

The NRC has added § 26.183(d)(ii) to the final rule to further specify the MRO's responsibilities for directing MRO staff. These responsibilities include, but are not 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. The MRO must also ensure that personal information about the donor is maintained confidentially with the highest regard for individual privacy. These requirements meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

The NRC has also added § 26.183(d)(1)(iii) 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 when 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, § 26.183(d)(1)(iii) establishes these clear limits and is consistent with Goal 3 of this rulemaking to improve the effectiveness of the FFD program.

The NRC has added § 26.183(d)(2) [MRO staff responsibilities] to specify the duties that MRO staff may and may not perform. The provisions are also based on the experience of other Federal agencies, which has indicated that clear limits on MRO staff duties are necessary to protect donor confidentiality and the integrity of the MRO process. Therefore, this addition is consistent with Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. Section 26.183(d)(2)(i) permits MRO staff to receive results from the HHS-certified laboratory and to review and report negative test results to the licensee's or other entity's designated reviewing official under the MRO's direction. Section 26.183(d)(2)(ii) permits MRO staff to review the custody-and-control forms for specimens that the laboratory reports as positive, adulterated, substituted, invalid, or dilute, and to correct errors. However, the MRO is required to review and approve the corrections. Section 26.183(d)(2)(iii) prohibits staff from conducting interviews with donors to discuss positive, adulterated, substituted, invalid, or dilute test results. The provision also prohibits

MRO staff from requesting or reviewing medical information from donors related to any positive, adulterated, substituted, dilute, or invalid test results.

Section 26.183(d)(2)(iv) prohibits MRO staff from reporting or discussing positive, adulterated, substituted, invalid, or dilute test results received from the HHS-certified laboratory with any individuals other than the MRO and other MRO staff. The provisions are necessary to protect donor confidentiality and the integrity of the MRO review process, consistent with Goal 7 of this rulemaking to protect privacy and other rights (including due process) of individuals who are subject to Part 26. At the same time, the provision permits licensees and other entities to realize the cost efficiencies associated with the MRO delegating some tasks to staff, consistent with Goal 3 of this rulemaking to increase the effectiveness and efficiency of Part 26 programs. With respect to the proposed rule, the NRC has clarified this provision to specify that the MRO staff may not report or discuss positive, adulterated, substituted, dilute, or invalid test results received from the HHS-certified laboratory with any individuals other than the MRO and other MRO staff before those results have been reviewed and confirmed by the MRO. The final rule also adds limitations on with whom the MRO staff can discuss confirmed positive, adulterated, substituted or invalid test results, as well as limitations on discussion of quantitative test results and any personal medical information. The NRC believes that only the MRO is qualified to answer questions from FFD program personnel about the basis for his or her decisions and the proper interpretation of test results from the HHS lab. These changes are consistent with Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.185 Determining a fitness-for-duty policy violation.

Section 26.185 of the final rule contains requirements related to the MRO's determination that a positive, adulterated, substituted, invalid, or dilute test result constitutes an FFD policy violation.

Section 26.185(a) [MRO review required] of the final rule amends portions of former Section 2.9(a) in Appendix A to Part 26. The former section established requirements for the MRO's review of test results from the HHS-certified laboratory. The final rule expands 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 are not limited to, reviewing positive, adulterated, substituted, dilute, or invalid 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 change meets Goal 3 of the rulemaking as it relates to improving the effectiveness of FFD programs and is consistent with the NRC's increased concern with potential subversion of the testing process, as discussed with respect to § 26.31(d)(3)(i). This provision also deletes the former reference to "nuclear power plant worker" and replaces it with "individual" because persons other than nuclear power plant workers are subject to the requirement. In addition, this provision eliminates the former requirement for the MRO to review blood test results from the HHS-certified laboratory because the rule no longer permits donors to request testing of a blood specimen for alcohol, as discussed with respect to § 26.83(a). However, the provision retains the former requirement that the MRO must complete the review of any positive, adulterated, substituted, invalid, and, at the licensee's or other entity's discretion, dilute test results before transmitting results to a licensee's or other entity's designated representative.

With regard to the proposed rule, the NRC received a public comment stating that the MRO should not be required to determine whether a donor has violated the FFD policy because MRO expertise is exclusively medical. The NRC believes that an MRO has the medical expertise and detailed knowledge of possible alternate medical explanations that is essential to the review process. Therefore, the NRC maintains that the MRO is required to determine whether a donor has violated the FFD policy.

Section 26.185(b) [Reporting of initial test results prohibited] of the final rule retains the intent of the requirement in the last sentence of former Section 2.9(a) in Appendix A to Part 26. Specifically, this provision continues to prohibit the MRO from communicating to licensees and other entities any positive, adulterated, substituted, dilute, or invalid 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, this provision extends the prohibition to MRO staff, consistent with Goal 7 of this rulemaking and the addition of requirements related to MRO staff in § 26.183(d), as discussed with respect to that provision.

Section § 26.185(c) [Discussion with the donor] of the final rule amends former Section 2.9(c) in Appendix A to Part 26. This provision continues to require the MRO to discuss a positive confirmatory drug test result with the donor before determining that the FFD policy had been violated. This provision adds a requirement for the MRO to discuss adulterated, substituted, dilute or invalid 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 rule, as discussed with respect to § 26.31(d)(3)(i). This provision also adds a reference to "other occurrence" to address circumstances when 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 Subpart E [Collecting Specimens for Testing]. This provision eliminates the former requirement for the MRO to contact the EAP. Under this provision, referral to the EAP is at the licensee's or other entity's discretion, as documented in FFD procedures. The NRC has eliminated the former requirement because most licensees terminate the employment of individuals who have a confirmed positive, adulterated, or substituted drug test result. It is 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, this provision requires the licensee or other entity to meet the applicable requirements of § 26.69 [Authorization with potentially disqualifying fitness-for-duty information]. The NRC has made these changes in the paragraph for consistency with other changes to the regulation and to meet Goal 3 of the rulemaking as it relates to increasing efficiency in FFD programs.

The NRC has added § 26.185(d) [Donor unavailability] to the final rule to clarify the circumstances when the MRO may confirm a positive, adulterated, substituted, dilute, or invalid test result, or other occurrence, as an FFD policy violation without having first discussed the test result or occurrence with the donor. These circumstances include when —

(1) The donor expressly declines the opportunity to discuss the possible FFD policy violation with the MRO, as specified in § 26.185(d)(1);

(2) The donor fails to contact the MRO within one business day after being contacted by the licensee or other entity, or an MRO staff member, as specified in § 26.185(d)(2); and

(3) The MRO is unable to contact the donor after making a reasonable effort to do so as specified in § 26.185(d)(2).

These provisions provide more detailed guidance than the first sentence of former Section 2.9(c) in Appendix A to Part 26 in response to many questions that have arisen regarding implementation of the requirement for MROs to discuss test results with the donor. The revisions also respond to stakeholders' requests during the public meetings discussed in Section I.D. In questions to the NRC staff and during the public meetings, licensees have pointed out that the former rule made no provision for these circumstances that do occasionally arise. Therefore, these provisions address these circumstances. The NRC believes that these provisions give the donor adequate opportunity to be contacted, consistent with Goal 7 of this rulemaking to protect the rights of individuals subject to Part 26, while allowing licensees to make "reasonable efforts" to contact the donor; thus meeting Goal 3 of this rulemaking as it

relates to improving efficiency in the FFD program.

For the same reasons, § 26.185(e) [Additional opportunity for discussion] of the final rule specifies procedures for addressing a circumstance when the donor was unable to be contacted by the MRO to discuss a positive, adulterated, substituted, dilute, or invalid test result, or other occurrence. This provision permits 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 permits the MRO to reopen the procedure for determining whether the donor had violated the FFD policy. This provision also permits the MRO to modify the initial determination based on the information that the donor provides.

The requirements in § 26.185(d) and (e) 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 provisions meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The NRC has added § 26.185(f) through (i) to the final rule to establish requirements for the MRO's review of validity test results. The NRC has added these paragraphs for consistency with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i) to meet Goal 3 of this rulemaking to increase the effectiveness and efficiency of Part 26 programs.

Section 26.185(f) [Review of invalid specimens] clarifies the MRO's responsibilities if the HHS-certified laboratory reports that a specimen is invalid. This provision is consistent with related provisions in the HHS Guidelines and is necessary because MRO actions in response to an invalid specimen are not specified in the former rule. Section § 26.185(f) provides the MRO with the following several alternative courses of action if a specimen is declared to be invalid by

the laboratory:

Section 26.185(f)(1) requires 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 shall direct the laboratory to forward an aliquot of the specimen to a second HHS-certified laboratory for further testing.

Section 26.185(f)(2) requires 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, this provision also requires 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. The licensee or other entity would then rely upon the results of the second test to make an authorization decision. This provision does not require the second specimen to be collected under direct observation in this situation because there is 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 MRO may

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 are not limited to, testing of alternate specimens, such as hair, oral fluids, or sweat. The NRC leaves the selection of an alternative method to the professional judgement of the MRO. This provision also prohibits 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.

Section 26.185(f)(3) requires 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 is warranted in this situation because the invalid specimen may be the result of a subversion attempt. This provision requires the licensee or other entity to rely on the test results from the directly observed collection in authorization decision-making because the result from the invalid specimen would be neither negative nor positive, adulterated, substituted, or invalid, and could not meet the requirements for granting authorization to an individual in Subpart C [Granting and Maintaining Authorization] or serve as the basis for imposing the sanctions specified in Subpart D [Management Actions and Sanctions].

The NRC has added § 26.185(g) [Review of dilute specimens] to the final rule to establish requirements for the MRO's review of positive confirmatory drug test results from dilute specimens. The NRC has added this paragraph because reviewing test results from a dilute specimen is complex and MRO actions in response to a dilute specimen are not addressed in the former rule.

Section 26.185(g)(1) requires 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. The final rule amends the proposed rule by clarifying that a clinical examination is one of the criteria that must be met before the MRO can confirm a drug-positive FFD violation, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rulemaking. 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 is required in § 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.

The final rule modifies and clarifies § 26.185(g)(2) of the former and proposed rules. This provision specifies the conditions that must be met in order for the MRO to determine whether the positive and dilute specimen is a refusal to test. These conditions include when —

(1) The HHS-certified laboratory conducts the special analysis of dilute specimens permitted in 26.163(a)(2) and the results show the presence of drugs or drug metabolites in the specimen;

(2) The MRO determines there is no legitimate medical explanation for the presence of drugs or drug metabolites in the specimen; and

(3) a clinical examination has been conducted in accordance with this section.

The provision also specifies when the MRO shall determine that drug test results are positive and the donor has violated FFD policy. These changes are consistent with the changes the NRC has made to procedures for processing dilute specimens, as discussed in § 26.163(a)(2).

Section 26.185(g)(2)(i) through (g)(2)(iii) defines the circumstances that may 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 § 26.185(g)(2). These circumstances are the same as those specified in § 26.115(a)(1) through (a)(3). The final rule clarifies this provision of the proposed rule by specifying that these circumstances must be considered by the MRO, if applicable, and are not the exclusive grounds to believe the donor may have diluted the specimen in a subversion attempt. This NRC has made this change in response to public comment and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.185(g)(3) clarifies that the MRO may also require the additional testing of a dilute specimen that is permitted in § 26.185(g)(2) if the specimen was collected under direct observation. This provision adds this permission for consistency with the related provisions in the FFD rule.

Section 26.185(g)(4) requires the MRO to determine whether there is clinical evidence of the illegal use of opiates or 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. This provision does not require an evaluation for clinical evidence of illegal use of opiates for 6-AM because its presence in a specimen is proof of heroin use. However, the provision does 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 paragraph (j) of this section) because the concentration of opiates in a dilute specimen does not bear any known relationship to the concentration of opiates in vivo (i.e., in the donor's body). For similar reasons, this provision also requires 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.

The NRC has added § 26.185(g)(5) to the final rule, with respect to the proposed rule, to specify the circumstances under which MRO review is not required. This change is consistent with related provisions in the HHS guidelines.

The NRC has added § 26.185(h) [Review of substituted specimens] to the final rule to establish requirements for the MRO review of substituted test results. These provisions have been added because MRO actions in determining an FFD policy violation for a substituted specimen are consistent with the related provisions in the HHS Guidelines and are not addressed in the former rule.

Section 26.185(h)(1) requires the MRO to contact the donor to determine whether there is a legitimate medical reason for the substituted result. This provision requires the MRO to give the donor the opportunity to provide legitimate medical evidence, within 5 business days of being contacted by the MRO, that he or she produced the specimen for which the HHS-certified laboratory reported a substituted result. The final rule, with respect to the proposed rule, specifies that a qualified and experienced physician, as verified by the MRO, shall submit the medical evidence. The NRC has made this change because after publishing the proposed rule, it recognized the need for additional clarity in this provision to specify the NRC's intent. This provision also provides 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.

Section 26.185(h)(2) directs 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.

Section 26.185(h)(3) directs 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.

Section 26.185(i) [Review of adulterated specimens] of the final rule establishes requirements for the MRO's review of adulterated test results. This provision has been added because MRO actions in determining an FFD policy violation for an adulterated specimen are not addressed in the former rule. Section 26.185(i)(1) requires the MRO to contact the donor and offer him or her the opportunity to provide an acceptable medical explanation for the adulterated result within 5 business days after the donor produced the adulterated result. The final rule, with respect to the proposed rule, specifies that a qualified and experienced physician, as verified by the MRO, shall submit the medical evidence. The NRC has made this change because after publishing the proposed rule, it recognized the need for additional clarity in this provision to specify the NRC's intent. If the MRO determines that there is no legitimate acceptable medical explanation for the adulterated result, § 26.185(i)(2) requires the MRO to report to the licensee or other entity that the specimen is adulterated. If the donor provides an acceptable medical explanation, § 26.185(j)(3) requires the MRO to report that no FFD policy violation had occurred. These requirements are consistent with the related provisions in the HHS Guidelines.

Section 26.185(j) [Review for opiates, prescription and over-the-counter medications] of the final rule amends former Section 2.9(d) in Appendix A to Part 26. It addresses circumstances that have arisen since Part 26 was first published and about which licensees have sought guidance from the NRC. These changes are consistent with Goal 3 of the rulemaking to improve the effectiveness of FFD programs. The paragraph amends the former requirements in Section 2.9(d) in Appendix A to Part 26 and adds others, as follows:

Section 26.185(j)(1) incorporates updated requirements from the HHS Guidelines related to the MRO's review of a positive drug test result for opiates. The rule revises but retains the meaning of the requirement for the MRO to determine that there is clinical evidence of illegal use of opiates, which appeared in former 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 rule permits the MRO to designate another licensed physician who has knowledge of the clinical signs of drug abuse to conduct the evaluation. This change ensures 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 change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

This provision eliminates the examples of clinical signs of opiate abuse in former Section 2.9(d) in Appendix A to Part 26 because these signs are addressed as part of the training that MROs must obtain in order to pass the comprehensive certification examination required in § 26.183(a) [Qualifications]. The rule retains the provision in former 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 rule adds 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 NRC has made this change because, in the experience of other Federal programs, such concentrations without a legitimate medical explanation can only indicate substance abuse. In addition, the rule prohibits 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 because food consumption could not result in a concentration at this level.

Section 26.185(j)(2) retains the last sentence of former Section 2.9(d) in Appendix A to Part 26. This provision requires the MRO to determine whether there is clinical evidence of abuse of these substances or their derivatives, in addition to the positive confirmatory test result.

The NRC has added § 26.185(j)(3) to the final rule 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 their determinations as to whether the use of another person's prescription medication is an FFD policy violation. The paragraph clarifies the NRC's intent with respect to these circumstances. In the final rule, if a donor claims, and the MRO confirms, that a positive, adulterated, substituted, or invalid drug test result is due to the unauthorized use of another person's prescription medication, the rule requires 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 shall 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 will confirm that the test results are positive for the drug or metabolites detected.

The NRC has added § 26.185(j)(4) to the final rule 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 their determinations as to whether the use of medications legally obtained in a foreign county is an FFD policy violation. The paragraph clarifies 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 rule permits 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 rule prohibits 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.

The NRC has added § 26.185(j)(5) 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 § 26.163, including, but not limited to hemp products and coca leaf tea. In so doing, the rule provides 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 DOT, 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 § 26.29(a)(6) and (a)(7), individuals who are subject to Part 26 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.

The NRC has added § 26.185(j)(6) to the final rule 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 prohibition is primarily 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 requirement is 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.

Section 26.185(k) [Results consistent with legitimate drug use] of the final rule amends former Section 2.9(f) in Appendix A to Part 26. The former provision instructed 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 former provision did 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 final rule requires that a determination of fitness must be performed. Because the MRO determined that the drug test result was negative, the licensee or other entity shall 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 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. By providing greater

assurance that individuals who are subject to the rule are fit to safely and competently perform their duties, the provision meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section 26.185(l) [Retesting authorized] of the final rule amends former Section 2.9(e) in Appendix A to Part 26. This provision permits the MRO to authorize retesting of an aliquot of a specimen or the analysis of any split specimen (Bottle B) if there is any question about the accuracy or scientific validity of a drug test result in order to determine whether the FFD policy has been violated. The final rule retains the provisions in former Section 2.9(e) that permitted 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 final rule updates the former requirement for consistency with the terminology used throughout the final rule (e.g., “Bottle B” to refer to a split specimen), as discussed with respect to § 26.5 [Definitions]. The final rule also includes a requirement that the retesting must be conducted at a second HHS-certified laboratory that did not conduct the original tests. The requirement that retesting must be performed at a second HHS-certified laboratory ensures the independence of the second testing and provide additional protection of donors’ due process rights under the rule. In addition, the requirement increases the consistency of Part 26 with related provisions in the HHS Guidelines, consistent with Goal 1 of the rulemaking to update and enhance the consistency of Part 26 with advances in other Federal rules and guidelines.

The proposed rule required the donor to request the retest in writing in order to ensure donors’ control over the specimen and rights to privacy under § 26.135(b). However, the final rule eliminates the provision that the donor’s authorization for re-testing must be in writing. This change is in response to public comment stating that obtaining a written request poses an unnecessary logistical burden on the donor and the MRO and that verbal requests are and have been sufficient in the past. Therefore, the NRC has made this change, consistent with

other Federal regulations and Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.185(m) [Results scientifically insufficient] of the final rule amends the first sentence of the former Section 2.9(g) in Appendix A to Part 26. This provision permits the MRO to determine that a positive, adulterated, substituted or invalid test result is scientifically insufficient for further action. The final rule instructs the MRO to report that the drug or validity test result is not an FFD policy violation in these circumstances, but that a negative test result was not obtained. The NRC has made this change for consistency with other changes in the rule related to invalid test results (see § 26.185(f). 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 positive, adulterated, or substituted test result. Therefore, the change meets Goal 6 of this rulemaking to improve clarity in the language of the rule. The NRC has changed some of the terminology used in the former paragraph in the final rule for consistency with the terminology used throughout the final rule (e.g., “samples” is changed to “specimens”). The final rule also makes the following changes to this provision:

The final rule also adds a statement to the former 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 final rule includes 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 positive, adulterated, substituted, or invalid. Although the NRC is not aware of any such instances in Part 26 programs, the rule clarifies that the MRO alone is authorized to request retesting to further protect the independence of the MRO function.

In addition, the NRC has moved the last sentence of former Section 2.9(g), which

contained records retention requirements, to § 26.215(b)(11) of Subpart N [Recordkeeping and Reporting Requirements] of the final rule. The NRC has moved this provision to group it with other records retention requirements in the rule for organizational clarity.

Section 26.185(n) [Evaluating results from a second laboratory] establishes 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. This provision specifies that the test result(s) from the second HHS-certified laboratory supersede the confirmatory test results provided by the HHS-certified laboratory that performed the original testing of the specimen. The final rule incorporates these requirements from the HHS Guidelines because the former rule did not address MRO actions in response to test results from a second laboratory. Therefore, the provision is consistent with the related provisions in the HHS Guidelines and meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The NRC has added § 26.185(o) [Re-authorization after a first violation] to the final rule. This provision addresses 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 former rule did not require the MRO to evaluate whether drug test results in these instances indicated subsequent drug use after a first confirmed positive drug test result, and MROs from different FFD programs have implemented different policies. Specifically, the final rule requires 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 provision prohibits 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 is inconsistent with additional marijuana use since the first positive, adulterated, substituted, or invalid 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 provision prevents individuals from being subject to a 5-year denial of authorization for a second confirmed positive drug test result under § 26.75(e), when the donor has not engaged in further drug use, consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process rights) of individuals who are subject to Part 26.

Section 26.185(p) [Time to complete MRO review] of the final rule amends former § 26.24(e). This provision 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 business days after an initial positive, adulterated or substituted test result. The rule replaces the former phrase, "initial presumptive positive screening test result," with the phrase, "initial positive, adulterated or substituted test result," for consistency with the terminology used throughout the rule (see § 26.5 [Definitions]). This provision also requires the MRO to report his or her determination that a 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 NRC has made these changes for consistency with the related provisions in the HHS Guidelines, consistent with Goal 1 of this rulemaking.

Section 26.187 Substance abuse expert.

The NRC has added § 26.187 [Substance abuse expert] to the final rule. This section establishes minimum requirements for a new position within FFD programs, the "substance abuse expert" (SAE). These added provisions meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.187(a) [Implementation] to the final rule. This provision requires SAEs to meet the requirements of this section within 2 years of the date on which the final rule is published in the Federal Register. The NRC has imposed the 2-year period 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. With respect to the proposed rule, the final rule adds a sentence that allows an MRO who meets the requirements of this section to serve as both an MRO and as an SAE. The NRC has made this change in response to a public comment suggesting that allowing the MRO, if qualified, the option to function as the SAE would avoid any unnecessary financial burden for licensees that have an MRO that can make SAE determinations.

The NRC has added § 26.187(b) [Credentials] to the final rule to establish the credentials required for an individual to serve as an SAE under this part. The rule requires that the SAE must possess the extensive education, training, and supervised clinical experience that are prerequisites for obtaining the professional credentials listed in § 26.187(b)(1) through (b)(5). Further, § 26.187(c) through (e) requires an SAE to possess additional knowledge and experience directly related to substance abuse disorders and the requirements of this part.

The NRC has added § 26.187(c) [Basic knowledge] and (d) [Qualification training] to the final rule to establish the specific areas of expertise and training that are required for an individual to serve as an SAE under this part. The knowledge and training requirements in these two paragraphs are necessary to ensure that SAEs possess the knowledge and clinical

experience required to perform the SAE function effectively in a Part 26 program.

Section 26.187(c) requires 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 § 26.187(c)(1); (2) knowledge of the SAE function as it relates to individuals who perform the duties that require an individual to be subject to this part, in § 26.187(c)(2); and (3) knowledge of this part and any changes to its requirements, in § 26.187(c)(3).

Section 26.187(d) establishes the topical areas in which an SAE must be trained. The qualification training requirements include training in the following areas: (1) the background, rationale, and scope of this part, in § 26.187(d)(1); (2) key drug and alcohol testing requirements of this part, in § 26.187(d)(2) and (d)(3), respectively; (3) SAE qualifications and prohibitions, in § 26.187(d)(4); (4) the role of the SAE in making determinations of fitness, and developing treatment recommendations and followup testing plans, in § 26.187(d)(5); (5) procedures for consulting and communicating with licensee or other entity officials and the MRO, in § 26.187(d)(6); (6) reporting and recordkeeping requirements of this part as they related to the SAE function, in § 26.187(d)(7); and (7) appropriate methods for addressing issues that SAEs confront in carrying out their duties under this part, in § 26.187(d)(8).

The NRC has added § 26.187(e) [Continuing education] to the final rule to ensure that SAEs maintain the knowledge and skills required to perform the SAE function. The paragraph requires 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. Section 26.187(e)(1) describes 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 § 26.187(d). Section 26.187(e)(2) requires 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 continuing education requirements are necessary to ensure that SAEs maintain updated knowledge and skills to continue performing the SAE function effectively under this part.

The NRC has added § 26.187(f) [Documentation] to the final rule to specify the records that the SAE must maintain in order to demonstrate that he or she meets the requirements of this section. The SAE is required to provide the documentation, as requested, to NRC representatives, and to licensees or other entities who 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 are also required to have access to this documentation. These requirements are 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. The final rule, with respect to the proposed rule, adds a cross-reference to ensure that this provision is consistent with the protection of information requirements in § 26.37 of this part.

The NRC has added § 26.187(g) [Responsibilities and prohibitions] to the final rule to specify the responsibilities of SAEs within a licensee's or other entity's FFD program and their limitations.

Section 26.187(g)(1) specifies at least three circumstances in which the SAE is responsible for making a determination of fitness under the rule. In § 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 § 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 § 26.69 [Authorization with potentially disqualifying FFD information] 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 § 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 § 26.77 [Management actions regarding possible impairment] 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 duties that require the individual to be subject to this part. Therefore, the NRC has added the paragraph for consistency with other related provisions in the rule.

The NRC has added § 26.187(g)(2) to the final rule to require the SAE to act as a referral source to assist an individual's entry into an appropriate treatment or education program. The provision also prohibits the SAE from engaging in any activities that could create the appearance of a conflict of interest. Section 26.187(g)(2)(i) prohibits 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, § 26.187(g)(2)(ii)(A) through (g)(2)(ii)(D) specifies circumstances in which the prohibition in § 26.187(g)(2)(i) does not apply. In general, the rule permits 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 provisions are 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.

The NRC has added § 26.189 [Determination of fitness] to the final rule to present in one section and amend former requirements related to the determination that an individual is fit to safely and competently perform the duties that require individuals to be subject to this part.

The final rule replaces the terms “medical assurance” and “medical determination of fitness” used in various sections of the former rule [e.g., § 26.27(a)(3), (b)(2) and (b)(4)] with the term “determination of fitness” as defined in this section. The NRC has made this change in terminology because the rule permits healthcare professionals other than licensed physicians to conduct determinations of fitness, as discussed with respect to § 26.187 [Substance abuse expert]. Therefore, the change meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.189(a) to the final rule. The first sentence of the paragraph defines the term “determination of fitness.” This term refers to the process entered when 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. The final rule amends this definition as it was proposed, due to public comment, to clarify the intent of the provision.

In general, the final rule requires 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 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 § 26.69(b)(4)] or whether the individual is a licensed physician. Therefore, § 26.189(a)(1) through (a)(5) provides examples of the healthcare professionals who are 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 are permitted to make determinations of fitness under § 26.189(a)(1). The final rule permits 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 § 26.189(a)(2), psychiatrists in § 26.189(a)(3), physicians in § 26.189(a)(4), or an MRO in § 26.189(a)(5), consistent with their professional qualifications. The final rule also permits other licensed and certified professionals who are not listed in the 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 are reserved for healthcare professionals who have met the specific training, clinical experience, and knowledge requirements for an SAE under § 26.187 [Substance abuse expert] for the reasons discussed with respect to that section.

The final rule also prohibits 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 rule adds 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 prohibition is necessary to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs, as well as Goal 7 to protect the privacy and other rights (including due process rights) of individuals who are subject to Part 26.

Section 26.189(b)(1) through (b)(4) of the final rule lists and presents together the circumstances in which a determination of fitness must be performed, as required in other sections of the rule. Although this paragraph is redundant with other sections of the rule, these circumstances are listed in one paragraph to meet Goal 6 of this rulemaking 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.

Section 26.189(b)(1) reiterates the requirement in former Section 2.9(f) in Appendix A to Part 26 and § 26.185(k) of the final rule that a determination of fitness must be performed when there is a medical explanation for a positive, adulterated, substituted, or invalid 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.

Section 26.189(b)(2) reiterates requirements in former § 26.27(b)(1) and (b)(4) and § 26.69(b) [Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization] of the final rule 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.

Section 26.189(b)(3) reiterates the requirement in § 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 the requirements of this subpart.

Section 26.189(b)(4) addresses 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 § 26.27(c)(4), and if a licensee's or other entity's reviewing official requires one, under § 26.69(c)(3) and (d)(2).

The NRC has added § 26.189(c) to the final rule to establish requirements for a determination of fitness that is conducted "for cause." Specifically, § 26.189(c) requires that a determination of fitness that is conducted for cause must be conducted through face-to-face interaction. With respect to the proposed rule, the final rule clarifies that a face-to-face interaction is required only when there is observed behavior or a physical condition. This provision ensures 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 NRC does not require a for-cause determination of fitness to be conducted under this section if there is an absence of physical or sensory information (i.e., based solely on receiving information that an individual is engaging in substance abuse). The immediacy of the decision limits the amount of information that can be gathered and made available to the professional by others. The provision does not require that determinations of fitness for other purposes be conducted face-to-face. These other purposes may include, but are not limited to, the determination of fitness that is 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. In these cases, 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, NRC has added the paragraph to meet Goal 3 of this

rulemaking to improve the effectiveness and efficiency of FFD programs. This provision also requires a face-to-face assessment in some circumstances where electronic means of communication could not provide the requisite information for the evaluation. It also permits 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.

Section 26.189(c)(1) through (c)(2) specifies the required outcomes of a for cause determination of fitness. The final rule provides 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 § 26.187 [Substance abuse expert].

Section 26.189(c)(1) requires 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. The licensee or other entity shall permit the individual to perform the duties that require the individual to be subject to this part.

Section 26.189(c)(2) requires 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 does not constitute a violation of Part 26 or the licensee's or other entity's FFD policy. Therefore, no sanctions shall be applied. Examples of circumstances in which an individual may be determined to be unfit under this 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 duties that require the individual to be subject to this part. In addition, the final rule requires 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.

The NRC has added § 26.189(d) to the final rule 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 paragraph also requires that the professional who made the initial determination must be responsible for modifications to the initial determination based on new or additional information. However, if the initial professional is no longer available, then the licensee or other entity is required to assist in arranging for consultation between a new professional and the professional who is no longer employed by or under contract to the licensee or other entity. The paragraph is necessary to ensure consistency and continuity in the treatment of an individual who may be undergoing treatment, aftercare, and followup testing. Therefore, this addition meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Subpart I – Managing Fatigue

Section 26.201 Applicability.

Section 26.201 specifies the licensees and other entities to whom the requirements in Subpart I apply. This section replaces, with limited editorial changes, § 26.195 of the proposed rule. Subpart I applies only to licensees who are authorized to operate a nuclear power reactor (under § 50.57 [Issuance of operating license] of this chapter) and holders of a combined license after the Commission has made the finding under § 52.103(g) [Operation under a combined license] of this chapter, as specified in § 26.3(a), and Contractors/Vendors (C/Vs)

who implement FFD programs or program elements upon which these licensees rely, as specified in § 26.3(c). As discussed in Section IV.D, the final rule requires 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 former NRC regulatory framework did not include consistent requirements to prevent worker fatigue from adversely impacting safe operations and the former requirements are difficult to readily and efficiently enforce.

(4) Reviews of nuclear power plant licensees' controls on work hours have repeatedly identified practices that are inconsistent with the NRC Policy on Worker Fatigue, including excessive work hours and the overuse of work hour limit deviations.

(5) The former regulatory framework was comprised of requirements that were inadequate and incomplete for effective fatigue management.

(6) Ensuring effective management of worker fatigue through rulemaking substantially enhances the effectiveness of FFD programs (i.e., the new requirements are cost-justified safety enhancements) 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 United States.

The requirements in the final rule also 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 final rule provision permits a licensee to rely on the fatigue management program of a C/V, which is consistent

with former § 26.23(a), so long as the C/V relies on licensee-approved FFD programs and program elements, as retained in § 26.3 [Scope].

Subpart I does not apply to the materials licensees who are otherwise subject to Part 26 (see § 26.3) for two reasons. First, NRC analyses indicate 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 NRC regulations require. Second, no analysis has been done to date to determine if there is evidence of excessive overtime use by the materials licensees. Therefore, at this time, the final rule does not impose the requirements of Subpart I on materials licensees. However, requirements to prevent fatigue from adversely affecting the job performance of security personnel at materials facilities provide a substantial enhancement to the security of these facilities. In SRM-COMSECY-04-0037, "Staff Requirements: Fitness-For-Duty Orders to Address Fatigue of Nuclear Facility Security Force Personnel," dated September 1, 2004, the Commission determined that FFD program 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.

Section 26.203 General provisions.

Section 26.203 establishes fatigue management requirements for licensees' FFD programs. This section replaces, § 26.197 of the proposed rule, with limited editorial changes. These editorial changes include the addition of recordkeeping requirements under § 26.197(d) and the removal of collective work hour requirements from § 26.197(e)(2) of the proposed rule. The general provisions in this section establish requirements for licensees' fatigue management policies, procedures, training, examinations, recordkeeping, and reporting. The NRC's

objective in establishing these general provisions is to facilitate integrating fatigue management into licensees' FFD programs, as discussed in Section IV.D.

Section 26.203(a) [Policy] requires 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. This section replaces § 26.197(a) of the proposed rule with limited editorial changes. The policy required in this section will apply to all individuals subject to the licensee's FFD program and not just those individuals subject to the work hour requirements presented in § 26.205 [Work hours], which contains the revised work hour requirements presented in proposed § 26.199. The NRC considers the responsibility for ensuring that each individual is fit to safely and competently perform his or her duties to be shared between the licensee and the individuals who perform duties on the licensee's behalf. Therefore, the final rule requires each licensee's FFD policy to delineate the licensee's fatigue management policy. Thus, individuals who are subject to this policy will be aware of and can comply with the fatigue management requirements for which they will be held accountable. The final rule requires each licensee to incorporate the fatigue management policy statement into the written FFD policy that is required under § 26.27(b) [Policy]. As discussed with respect to § 26.27(b), the final rule requires 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 a need exists for individuals to clearly understand their own fatigue management responsibilities, as well as those of the licensee. These responsibilities include the individual's duty 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 duties, as well as concerns related to others, and the licensee's obligation to assess such fatigue-related FFD concerns. Further, the final rule does not prohibit licensees from imposing sanctions on individuals who fail to comply with the portions of the licensees' fatigue management policies that assign certain responsibilities to individuals. For example, a licensee 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 § 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 final rule does not establish minimum sanctions for specific 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, to protect an individual's rights under the rule, it is necessary for a licensee's fatigue management policies to communicate any sanctions that the licensee may impose on an individual for failing to comply with the policy's requirements.

Section 26.203(b) [Procedures] requires each licensee to develop, implement, and maintain procedures to carry out the fatigue management policy that § 26.203(a) [Policy] requires. Procedures are necessary to ensure that licensees' fatigue management programs are properly and consistently implemented. This section replaces, § 26.197(b) of the proposed rule, with limited editorial changes.

Section 26.203(b)(1) requires licensees to develop, implement, and maintain procedures that describe the process that an individual subject to the licensee's FFD program should follow when reporting to a supervisor that he or she is unfit for duty because of fatigue (i.e., he or she makes a self-declaration). In RIS 2002-007, the NRC noted that self-declaration is an important

adjunct to behavioral observation in meeting the requirements of the performance objective in former § 26.10(b) (as retained in § 26.23(c)), which is "to provide reasonable measures for the early detection of persons who are not fit to perform the 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 FFD (e.g., formally stating to a supervisor, "I am too tired right now to check these valve lineups accurately").

Section 26.203(b)(1)(i) requires the licensee's self-declaration procedure to describe the responsibilities and rights of individuals and licensees and the actions they must take with respect to an individual's self-declaration of fatigue. The licensee's self-declaration procedure may explain the employees' right to know what is going to happen to them if they self-declare, including any sanctions that may be imposed on them. The procedure may also describe the employees' right to privacy regarding the causes for the self-declaration. This section ensures that all parties involved in the self-declaration process understand the process and responsibilities and the extent and limitations of their rights related to self-declaration. The NRC has considered industry experience with individuals refusing to report to work on the basis that they were too tired. The NRC 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 § 26.211(b) for the reasons discussed with respect to that section, (2) the individual's responsibility to cooperate with the fatigue assessment process by providing the necessary information (see the discussion of § 26.211(c)(2)), and (3) the

licensee's responsibility for conducting a fatigue assessment in response to an individual's self-declaration, as required under § 26.211(a)(2), to determine whether, and under what controls and conditions if any, the individual is permitted or required to work. Section 26.211 [Fatigue assessments] retains with, limited editorial changes, the requirements in proposed § 26.201 [Applicability].

Section 26.203(b)(1)(ii) requires the licensee's self-declaration procedure to describe requirements for establishing controls and conditions under which an individual is 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 ensures correct and consistent implementation of the requirements in § 26.211(b), which states that a supervisor or staff member of the FFD program must conduct the fatigue assessment and determine whether, and under what conditions, an individual who has self-declared can be returned to duty. For example, the licensee's procedure will 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 will include, but will 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 is 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.

Section 26.203(b)(1)(iii) requires licensee procedures to describe the processes to be followed if an individual disagrees with the results of a fatigue assessment conducted in response to the individual's self-declaration. These procedures will 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 duties listed in § 26.205(a) [Individuals subject to work hour controls] 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 final rule adds this requirement for several reasons. First, in RIS 2002-007, the NRC documented concerns associated with past instances of self-declaration. These instances indicate 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 the preamble to the proposed rule, several stakeholders asked the NRC to add this provision to the final rule to ensure that individuals have recourse if they disagree with the results of a fatigue assessment 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 agrees that licensee policies and procedures related to implementing the requirements of this subpart must address these potential issues to protect the rights of individuals subject to the rule. However, the final rule does 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) the wide variety of

possible issues that may arise limits the ability of a single mechanism established in the final rule to appropriately address them all. Therefore, the final rule requires licensees to have procedures for addressing situations in which an individual who has self-declared disagrees with the outcome of a fatigue assessment, but it does not require a new process or specify the required characteristics of the licensees' process(es).

Section 26.203(b)(2) requires licensees to develop, implement, and maintain procedures that describe the process for implementing the work hour requirements in § 26.205 [Work hours]. For example, the procedures will detail individual and organizational responsibilities and requirements, including items such as scheduling, tracking and calculating work hours, granting waivers from the individual work hour requirements, reviewing the implementation of the work hour requirements, documenting the results of the reviews, and implementing any necessary corrective actions. These procedures are necessary to ensure that individuals understand the work hour requirements to which they are subject and that licensees consistently implement the work hour requirements in § 26.205 as the NRC intends.

Section 26.203(b)(3) requires licensees to develop, implement, and maintain procedures that describe the process(es) they will follow in conducting a fatigue assessment, as required under § 26.211(a). These procedures will establish the methods by which the licensee will determine whether an individual is fatigued, whether the individual 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 will address fatigue assessments that are conducted following an individual's self-declaration or 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 final rule requires licensees to conduct fatigue assessments are discussed in § 26.211(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 found to have been asleep while on duty), comprehensive procedures are necessary to ensure consistent implementation of the fatigue assessment requirements in § 26.211 [Fatigue assessments]. Therefore, the NRC expects these procedures to 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 can 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 § 26.205(e)(1)(iii). These procedures are necessary to implement the requirements in this subpart and protect the privacy rights and other rights of individuals, consistent with Goal 7 of this rulemaking.

Section 26.203(b)(4) requires licensees to develop, implement, and maintain procedures that describe the sanctions they may impose on individuals, if any, following a fatigue assessment (e.g., termination or leave without pay) and the conditions and considerations for imposing those sanctions. During the public meetings discussed in the preamble to the proposed rule, 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 FFD. Although the NRC neither endorses nor prohibits the imposition of sanctions in cases of fatigue, clear communication regarding possible sanctions and the considerations for taking those sanctions is necessary for individuals to meet their responsibility for self-declaration without unwarranted fear of potential outcomes. For this reason, procedures are necessary to ensure that licensees fully disclose the conditions under which sanctions will 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 § 26.39 [Review process for fitness-for-duty policy violations].

Section 26.203(c) [Training and examinations] establishes fatigue-related training and examination requirements in addition to those required under § 26.29(a) [Training content] and (b) [Comprehensive examination]. This section retains without change the requirement in § 26.197(c) of the proposed rule. Several of the knowledge and abilities (KAs) requirements listed in § 26.29(a) ensure that individuals are familiar with a licensee's or other entity's fatigue policies and procedures. However, individuals who are 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 final rule requires licensee FFD training and testing programs to address the topics specified in § 26.203(c)(1) and (c)(2).

Section 26.203(c)(1) requires FFD training and examinations to ensure that individuals who are subject to Subpart I 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 will address that are related to this KA will 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 Circadian Technologies, Inc. survey of 550 facilities in the United States and Canada found that turnover at facilities with operations extending beyond 7 a.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, Inc., 2004).

Section 26.203(c)(2) requires FFD training and examinations to ensure that individuals who are subject to 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 will 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 is 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 § 26.209 [Self-declarations] and § 26.211(a)(2), and to determine when it is appropriate to report an FFD concern about another individual who,

based on behavioral observations, is exhibiting indications of fatigue, as required under § 26.33 [Behavioral observation].

Section 26.203(d) [Recordkeeping] establishes recordkeeping requirements related to the implementation of Subpart I. This section includes, with revisions, the requirements presented in § 26.197(d) of the proposed rule. Specifically, § 26.203(d)(1), which retains § 26.197(d)(1) of the proposed rule without change, requires licensees to retain records of the number of hours worked by individuals who are subject to the work hour requirements established in § 26.205 [Work hours]. Section 26.203(d)(2) requires licensees to retain records of shift schedules and shift cycles of individuals who are subject to the work hour requirements established in § 26.205. The NRC added this requirement to the final rule. Section 26.203(d)(3) through (d)(5) retains the requirements in proposed § 26.197(d)(2) through (d)(4) without changes. Specifically, § 26.203(d)(3) requires licensees to retain records of the number of, and the bases for, waivers they have granted, § 26.203(d)(4) requires licensees to retain documentation of the work hour reviews that are required under § 26.205(e)(3) and (e)(4), and § 26.203(d)(5) requires retaining documentation of any fatigue assessments licensees conduct. The NRC removed the proposed § 26.197(d)(5) from the final rule because the NRC eliminated the collective work hour requirements. The final rule establishes these recordkeeping requirements for four reasons: (1) these records are 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 work hour requirements and waiver and fatigue assessment provisions, (2) the documentation is necessary for a review process under § 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 is necessary to perform the trending and self-assessments that § 26.205(e) [Reviews] requires; and (4) the documentation is necessary to meet the reporting requirements

in § 26.203(e) [Reporting]. To ensure that the records remain available for NRC inspections and the review process or legal proceedings, the final rule requires licensees to retain these records for 3 years or until the completion of any related legal proceedings, whichever is later.

Section 26.203(e) [Reporting] requires licensees to report to the NRC certain data related to their fatigue management programs as part of the annual FFD program performance report, which § 26.717 [Fitness-for-duty program performance data] requires. This requirement replaces, with revisions, § 26.197(e) of the proposed rule. This section is revised to specify that reports are required in a standard format. The final rule requires licensees to include the following information in the annual report: (1) information on the number of waivers granted from work hour requirements in the previous calendar year, and (2) the number of fatigue assessments conducted during the year, the management actions that resulted, and the conditions under which the fatigue assessments were conducted. This section does not retain the requirements in the proposed § 26.197(e)(2) for the reporting of information pertaining to the control of collective work hours because the final rule does not include collective work hour limits.

The NRC considered comments that the requirements for including fatigue management information should be deleted from the rule because they will not provide new or unique information to the NRC, are unnecessary to protect public health and safety, are unnecessary to facilitate NRC oversight of the revised rule, and are unduly burdensome. In choosing to retain reporting requirements for waiver use, the NRC considered several aspects of the work hour requirements in the final rule. First, the NRC established the work hour limits in the final rule at levels such that the potential for fatigue is substantive for individuals working in excess of those limits. Second, the rule permits licensees to authorize waivers of the limits only for circumstances in which the additional work hours are necessary to prevent or mitigate a condition adverse to safety or security. Finally, the rule only requires a waiver if the individual is

operating or maintaining an SSC that a risk-informed evaluation process has shown to be important to the protection of public health and safety or if the individual is performing specified functions that are essential to an effective response to a fire, plant emergency, or implementation of the site security plan. As a result, information concerning licensee use of waivers indicates (1) the number of hours worked on risk-significant activities by individuals at increased potential for impairment, and (2) how often a licensee must mitigate or prevent a condition adverse to safety while using individuals at increased potential for impairment. The NRC considers this unique information, not otherwise reported, to be relevant to the agency's mission.

The NRC similarly considered the need to retain reporting requirements regarding fatigue assessment and any management actions in response to the fatigue assessments. The final rule requires fatigue assessments (1) for cause, following an observation indicating impaired alertness; (2) post event, following a plant event or worker injury meeting specified significance criteria; (3) following a self-declaration of being unfit for duty; and (4) when a licensee returns an individual to duty with a break of less than 10 hours after the individual was relieved of duties because of a fatigue assessment conducted for cause or in response to a self-declaration of fatigue. With regard to fatigue assessments following self-declarations, the NRC notes that individuals are only assessed when a licensee denies a worker's request for relief from duty (i.e., a rest break). In all other instances, the individual will be allowed time off from duty under the licensee's administrative practices and will not require a fatigue assessment. Given these requirements of the final rule, licensee annual reporting of information pertaining to fatigue assessment will indicate how often (1) individuals are relieved of duty because of observed impairment from fatigue, (2) fatigue is identified as a causal factor in significant plant events and injuries, (3) individuals are required to remain on duty following their declaration that they are not fit for duty because of fatigue, and (4) individuals are returned

to duty with less than a 10-hour break following a for-cause assessment for fatigue or a self-declaration of fatigue. The NRC considers this unique information, not otherwise reported, relevant to the agency's mission, particularly when reviewed in concert with information concerning the licensee's use of waivers from the work hour limits.

The NRC expects that the information provided by licensees in response to the annual reporting requirements in Subpart I will facilitate NRC oversight of the implementation of the requirements through the following means:

- Consistency, efficiency, and continuity of NRC oversight—Information provided through the annual FFD program performance reports concerning fatigue management will enable the NRC to achieve a higher level of consistency and efficiency in the oversight of the implementation of the requirements in Subpart I and in the enforcement of those requirements. Without the reporting requirements, the NRC's inspection of licensee FFD programs would likely be limited to individual inspectors evaluating licensee fatigue management for a sample of workers at a site for a limited time period. These assessments would necessarily be conducted without the benefit of broader contextual information of the site and industry normative information that would be available through the annual reports. In contrast, the annual reports will help ensure a common perspective and maintain consistency among inspectors conducting the oversight process. In addition, the annual reports can enhance the efficiency of the NRC inspection process by providing information necessary to allow the agency to focus inspection resources on duty groups (e.g., security or maintenance) or issues (e.g., self-declaration) that may warrant review. The reports will enable the NRC to be better focused in preparing for the inspection, reduce the burden of onsite inspection hours, and potentially reduce the total number of hours required for a baseline inspection. Furthermore, the annual reporting will also help to achieve a more complete and

continuous assessment of licensee performance because the NRC intends to conduct the baseline inspection of FFD programs only once every 2 years.

- Evaluation of rule implementation for lessons learned—Although the NRC and stakeholders have made extensive efforts to ensure clear and enforceable requirements that are effective and practical for the management of worker fatigue, the rule introduces the potential for unintended consequences and lessons learned. In addition, changes in the size and composition of the nuclear industry may have unforeseen implications for site staffing and fatigue management. The NRC expects that the site-specific and normative information obtained through the annual reports can provide important insights regarding opportunities to amend the rule to improve its effectiveness or reduce unnecessary burden. The NRC notes that such information was the basis for reducing the random testing rate for drugs and alcohol required in the final rule.
- Consistent interpretation of waiver criterion—The final rule provides licensees the discretion to use waivers to exceed the work hour limits, thereby allowing levels of work hours that could adversely affect worker FFD. The principal basis for allowing waivers is to reduce the additional staffing burden that licensees would otherwise incur if waivers were not available to address exigent circumstances. The annual reporting of waiver use in conjunction with the reporting of information concerning fatigue assessments will enable the NRC to ensure that licensees use this discretion in a manner consistent with the objectives of the rule and not as a means to compensate for a lack of adequate staffing. Furthermore, although the use of waivers is limited to conditions when the work hours are “necessary to prevent or mitigate a condition adverse to safety or security,” the NRC recognizes the potential for licensees to develop different interpretations regarding this criterion. Some industry commenters on the proposed rule took exception to the NRC’s characterization of high levels of waiver use at some sites as abuse.

These commenters suggested that differences in licensee waiver practices could be attributed to the policy being subject to a number of interpretations during the many years that it has been in effect. Regardless of the cause of the differences in licensee use of work hour control waivers, the NRC considers it prudent to address, through rulemaking, the lessons learned from past implementation of the policy and provide a level of oversight through the annual reporting requirement that will ensure consistent implementation of the waiver criteria in the future.

In addition to the reasons cited in the preceding paragraphs explaining the need for reporting requirements to ensure the effective and efficient oversight of the implementation of the rule, the NRC considers the reporting requirements to be justified and beneficial for the following additional reasons:

- Consistency with Part 26 requirements and performance objective—The final rule retains the requirement that licensees report the results of drug and alcohol testing and the performance objective for reasonable assurance that individuals are not impaired from any cause (§§ 26.719 [Reporting requirements] and 26.23(b) of the final rule, respectively). In addition, several studies discussed in detail in Section IV.D of this document have demonstrated that worker fatigue can produce levels of impairment that are comparable to blood alcohol concentrations above the levels permitted by this rule. Furthermore, given the frequency of worker concerns regarding fatigue and the work scheduling practices that are common during outages, the incidence of impairment from fatigue is likely to be greater than the very low incidence of drug and alcohol use that is detected through testing. The NRC therefore considers the reporting of information pertaining to licensee management of worker fatigue to be consistent with (1) the requirements for reporting information pertaining to drug and alcohol testing, (2) the performance objective of this rulemaking for licensees to implement a comprehensive

FFD program, and (3) the NRC's belief that the management of worker fatigue is no less important to worker FFD than the effective detection and deterrence of drug and alcohol use.

- Public confidence—Public interest groups such as the UCS and the Project on Government Oversight have commented at public meetings that relevant information regarding worker fatigue is withheld to either protect alleger identity or, in the case of security personnel, plant security. In addition, several public media articles have been published during the past 2 years reporting instances of guards sleeping and guards fearing repercussions for refusing forced and excessive overtime. Information submitted by licensees in the annual reports will be publicly available and will reassure public stakeholders that the NRC is appropriately cognizant of licensee actions regarding fatigue management and that the NRC's oversight of these activities is transparent to all stakeholders.
- The burden is limited and justified—Section 26.203(e) requires licensees to report information concerning waiver use and fatigue assessments as part of the annual FFD program report. As a result, the burden associated with this reporting requirement is an incremental change to the reporting requirement for drug and alcohol testing. In addition, the fatigue management information required by § 26.203(e) is largely information that licensees will have already generated to demonstrate compliance with other provisions of Subpart I. As a result, the burden associated with the report will be largely associated with compiling the information in an appropriate form and reviewing that compilation. The NRC has reviewed the public comments suggesting that the agency underestimated the number of clerical and management hours associated with this requirement and has taken these comments into consideration in estimating the burden of the reporting requirements in § 26.203(e) of the final rule. Nevertheless, the

NRC considers the burden associated with the annual reporting requirements to be justified for the reasons described in this and the preceding paragraphs.

The NRC also considered comments that the reporting requirement ignores significant duplication in licensee efforts. The NRC agrees that § 26.205(e) of the final rule requires licensees to periodically review and assess the effectiveness of the work hour controls and that the licensee's corrective action program, which is routinely inspected by the NRC, will document and trend these reviews. However, as noted previously, the NRC considers the annual reports to be a limited burden that will enable the NRC to provide more effective and consistent oversight and achieve other objectives for the effective implementation of the requirements in Subpart I.

Section 26.203(e)(1) requires licensees to provide the NRC with an annual summary of all instances during the previous calendar year in which the licensee waived each of the work hour controls specified in § 26.205(d)(1) and (d)(2) for each of the duties listed in § 26.4(a)(1) through (a)(5). This section revises the requirements in proposed § 26.197(e)(1). The agency revised this reporting requirement in response to comments that the required information would not provide a meaningful indication of licensee performance in managing work hours because a number of valid conditions may warrant waivers of work hour controls.

Section 26.203(e)(1) revises the reporting requirements in proposed rule § 26.197(e)(1) to clarify that licensee are required to report the number of waivers for each work hour requirement and not the sum total of all waivers for all work hour requirements. For example, if the licensee permits 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 will report that it granted three waivers of § 26.205(d)(1)(i), one waiver of § 26.205(d)(1)(iii), and one waiver of § 26.205(d)(2)(i), for the operations group that year. This clarification ensures that the waiver information is reported at

a level of detail that will enable the NRC to know which limits are most frequently exceeded and therefore better understand the specific scheduling challenges to licensee management of worker fatigue.

Section 26.203(e)(1) also requires licensees to include only those waivers under which work was actually performed in the annual report. This section contains requirements presented in § 26.197(e)(1)(i) of the proposed rule. The final rule retains this provision of the proposed rule 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 of the work hour controls listed in § 26.205(d)(1) and (d)(2) in order to complete a task and so will implement the process specified in § 26.207 [Waivers and exceptions] 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 final rule requires licensees to exclude waivers under which no work was performed from the annual report because this circumstance provides no meaningful information about the licensee's management of fatigue during extended work periods.

Section 26.203(e)(1) further specifies that licensees shall report all waivers granted for each of the work hour controls in § 26.205(d)(1) through (d)(5) for those instances in which a single extended work period required a waiver of more than one work hour control. This section contains the requirements presented in § 26.197(e)(1)(ii) of the proposed rule. For example, if an individual works 12 hours on day 1 and on day 2 the licensee needs the individual to work more than 16 hours to resolve a condition adverse to safety, the licensee would need to authorize and report a waiver of § 26.205(d)(1)(i), for exceeding 16 hours in a 24-hour period, and (d)(1)(ii), for exceeding 26 hours in a 48-hour period. Although this example included only one work period, both waivers are required and must be reported because the potential for

fatigue results not only from the length of the work day (e.g., exceeding 16 hours of work in a 24-hour period) but also the cumulative effect of prior work (e.g., exceeding 26 hours of work in a 48-hour period).

Section 26.203(e)(1)(i) and (e)(1)(ii) requires licensees to report whether work hour controls are waived for individuals working on normal plant operations or working on outage activities. In establishing this requirement the NRC considered comments that the use of waivers should be considered in context. Through its review of authorized waivers from the work hour limits in plant technical specifications, the NRC has found that waivers are most frequently associated with outage activities. Accordingly, the NRC has revised the final rule to require licensees to report whether a waiver of the work hour requirements in § 26.205 was associated with an outage activity. This revision will enable the NRC to better understand a site's changes in waiver use over time and understand why certain annual reports for a given site may indicate a heightened level of waiver use relative to the site's other reports.

The NRC recognizes that outages are not the only cause of waivers, however, the agency expects that most other causes of waiver use will be for substantially shorter periods of time or involve smaller groups of workers and that these other conditions would not have a substantive effect on overall waiver use. For unique causes that may have more substantive effects (e.g., licensee response to hurricanes), the NRC is likely to be aware of or able to identify these conditions if they were to significantly affect waiver use. Furthermore, the NRC intends to consider waiver use in conjunction with the reported fatigue assessment information. Therefore, the agency will be able to determine whether waiver use may be associated with the incidence of fatigue assessments conducted for cause, following events, or in response to self-declarations by individuals asserting that they are not able to safely and competently perform their duties because of fatigue. The NRC notes that the frequency of waiver use (i.e., how often individuals exceed the work hour limits while performing functions important to safety

and security) indicates the potential for worker fatigue to affect the performance of these functions, regardless of whether a waiver is the result of an activity associated with an outage or a cause that is beyond the licensee's control.

Section 26.203(e)(1)(i) requires licensees to report the number of instances in which each work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), and (d)(3)(i) through (d)(3)(iv) was waived for individuals not working on outage activities. Section 26.203(e)(1)(ii) requires licensees to report the number of instances in which each work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(iv), and (d)(4) and (d)(5)(i) was waived for individuals working on outage activities. The differences between § 26.205(e)(1)(i) and (e)(ii) in the work hour requirements specified reflects whether requirements are applicable to outage activities.

Section 26.203(e)(1)(iii) requires licensees to report a summary that shows the distribution of waiver use among the individuals within each category of individuals § 26.4(a) identifies. This summary will show, for example, how many individuals received only one waiver during the reporting period, how many individuals received two waivers, how many received three waivers, and so on. This reporting requirement enables the NRC to determine the extent to which waivers are concentrated among a few individuals or distributed more broadly within a group of individuals who perform the same duties. The NRC incorporated this requirement in the final rule in response to comments that the rule should also require licensees to report the number of workers covered under § 26.199(a) of the proposed rule to provide an appropriate context for the annual reporting of waivers. The NRC understood that the intent of this comment was to provide a basis for evaluating the number of waivers from the work hour controls relative to the number of individuals subject to those controls. The NRC chose not to require licensees to report the number of individuals covered under § 26.4(a) of the final rule because that number will vary throughout the course of the reporting period, particularly when

the reporting period includes a unit outage. In addition, the NRC believes that the required distribution of waivers more effectively provides context to the waiver use by indicating if the waivers were concentrated among individuals performing a certain duty and if the waiver use in a duty group was associated with relatively few individuals or distributed among many individuals.

The waiver data that licensees are required to report to the NRC under § 26.203(e)(1)(i) through (e)(1)(iii) are important because waivers represent "assumed risk." As discussed in Section IV.D, fatigued workers experience impaired cognitive functioning, including difficulties in decisionmaking and maintaining attention. 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 decisionmaking from fatigue. These performance degradations can be mitigated by establishing controls and conditions under which the individual is permitted to work, as required under § 26.211(e). However, controls and conditions can reduce, but not eliminate, the potential risks from fatigue-induced errors. The more often that a licensee permits individuals to exceed work hour limits, the more risk from fatigue-induced errors a licensee is assuming. The risk of fatigue-induced errors increases further when an individual is permitted to exceed more than one of the work hour limits contained in § 26.205(d)(1)(i) through (d)(1)(iii) because of the potential for the combined effects of both acute and cumulative fatigue. Any waivers from the rest breaks that are required under § 26.205(d)(2) or the minimum day off requirements of § 26.205(d)(3) through (d)(5) will 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 in evaluating FFD program performance.

Section 26.203(e)(2)(i) through(e)(2)(iv) requires 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, after an event, or as a followup, as described in § 26.211(a)(1) through (a)(4)), the type of work being performed by the individual as described in § 26.4(a) through (c), and the management actions that resulted from each assessment. To better ensure that the reported fatigue assessments can be considered in context, the NRC revised the requirement to also require licensees to report whether an individual assessed for fatigue was engaged in an outage-related activity at the time of the event or condition that resulted in the need for such an assessment.

The NRC considers the reporting of the fatigue assessments and their outcomes to be consistent with the requirement of § 26.717 [Fitness-for-duty program performance data] for reporting of drug and alcohol test results. 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 identified in § 26.23(c) to provide for the early detection of individuals who are not fit to perform the duties that require them to be subject to this part. The NRC similarly views the number of for-cause fatigue assessments that a licensee conducts each year to be another indicator of the health of the licensee's behavioral observation and self-declaration processes with respect to fatigue. Annual reports, which will include the distribution of waiver use among individuals performing the same duties, will enable NRC to determine the extent to which waivers are concentrated among a few individuals or distributed broadly among individuals within each category specified in § 26.4.

Collectively, the reporting of waivers required in § 26.203(e)(1) and the number of fatigue assessments conducted and their outcomes required in § 26.203(e)(2) provides

important information concerning the effectiveness of fatigue management at a licensee site. The reports 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 Subpart I in controlling the fatigue of nuclear power plant workers, (4) assess whether the objectives of the final rule are being achieved, and (5) determine whether any further changes to the requirements are necessary to ensure that worker fatigue is managed consistent with the intent of the provisions.

Section 26.203(f) [Audits] requires the licensee to audit the management of worker fatigue as part of the overall FFD program audits required in § 26.41 [Audits and corrective action]. This section does not add a new requirement, but is included in Subpart I for clarity.

Section 26.205 Work hours.

The NRC substantively revised § 26.199 of the proposed rule in response to public comments. The revised provisions are in § 26.205 [Work hours] of the final rule and establish controls on the work hours of select individuals who are subject to nuclear power plant licensees' FFD programs, as follows.

Section 26.205(a) [Individuals subject to work hour controls] establishes the scope of individuals who are subject to the work hour requirements in § 26.205. These individuals are subject to the work hour requirements, in addition to the training, behavioral observation, and self-declaration requirements of Subpart I that apply to all individuals who are subject to nuclear power plant licensees' FFD programs. In determining the scope of personnel who are subject to the 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 rule requires that individuals who perform the duties specified in § 26.4(a)(1) through (a)(5) must be subject to work hour controls. The duties specified in § 26.4(a)(1) through (a)(5) are the same as the duties that were specified in § 26.199(a)(1) through (a)(5) of the proposed rule. Rather than list the duties in § 26.205(a), the final rule references § 26.4(a) which provides a consolidated list of individuals subject to the requirements of Part 26.

Section 26.205(a) requires that individuals identified in § 26.4(a)(1) (i.e., 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 work hour requirements in this section. To implement the work hour requirements, nuclear power plant licensees are required to delineate the operations personnel who are subject to the work hour requirements, on the basis of the risk significance of the safety SSCs being operated. At a minimum, this must include 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 duty group, licensees can use, for example, the risk-significance determination process and criteria that they currently employ 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 requirements of § 26.205 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 work hour requirements would apply to the individuals who most directly affect the operation of those SSCs 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 duties specified in § 26.4(a)(1) 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, "Operators' Licenses," 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. Section IV.D discussed the effects of fatigue on decisionmaking, risk-taking, communications, and other key skills. Fatigued operators have an increased potential to commit errors, raising 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, decisionmaking) 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 than 600 hours of overtime in a year (Attachment 1 to SECY-01-0113, "Rulemaking Plan: Fatigue of Workers at Nuclear Power Plants"). 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 a sample of 37 refueling outages conducted in 1999, licensees authorized more than 1800 deviations for licensed operators and more than 1100 deviations 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 requirements in § 26.205 also apply to individuals who direct risk-significant operations on site. These individuals 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 requirements 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, decisionmaking, 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, particularly 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.

Section 26.205(a) [Individuals subject to work hour controls] requires that individuals identified in § 26.4(a)(2) (i.e., individuals who are maintaining or providing onsite direction for the maintenance 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 work hour requirements in this section. To implement this requirement, licensees are required to delineate the maintenance personnel, as well as the personnel who direct maintenance on site, who would be subject to the work hour controls on the basis of the risk significance of the SSCs that they maintain. At a minimum, this must include 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 can use, for example, the risk-significance determination process and criteria that they currently employ 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 requirements of § 26.205 would typically apply to individuals who are maintaining or directing on site the maintenance of SSCs that are included within the scope of an assessment required by § 50.65(a)(4). Therefore, the work hour requirements 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 or using non-conservative work practices, (2) making errors that would increase the risk of failure of the affected SSCs to perform their functions 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 rule requires these maintenance personnel to be subject to the work hour requirements to ensure that fatigue does not compromise their abilities to safely and competently perform their duties relative to the maintenance of these SSCs.

The work hour requirements also apply to those who direct risk-significant maintenance on site. For example, these individuals include maintenance supervisors who provide direction to maintenance technicians and engineers who provide onsite technical direction to maintenance crews, during key outage maintenance activities. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem solving, decisionmaking, 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, particularly 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.

Section 26.205(a) requires that individuals identified in § 26.4(a)(3) (i.e., individuals who perform health physics or chemistry duties that are required of the onsite emergency response

organization minimum shift complement) must be subject to the work hour requirements of this section. Although § 26.207(d) [Plant emergencies] exempts licensees from applying the work hour controls during declared emergencies, the intent of this provision is 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 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, Revision 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," issued March 2002, identifies the need for an on-shift chemistry/radiochemistry emergency response capability. An on-shift chemistry technician(s) provides 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 offsite 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.

Section 26.205(a) requires that individuals identified in § 26.4(a)(4) (i.e., 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) must be subject to the work hour requirements of this section. The work hour requirements are 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 decisionmaking 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 to maintain the 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 decisionmaking 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 decisionmaking 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.

In addition, the NRC periodically grants exemptions from the requirements of Appendix R [Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979] to

10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” 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 so that they are able to safely and competently perform their duties in plant events involving a fire.

Section 26.205(a) requires that individuals identified in § 26.4(a)(5) (i.e., 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) must be subject to the work hour requirements of this section. Individuals who perform these duties are the members of licensees’ security forces who are responsible for implementing the licensees’ physical security plans. 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. In contrast to most other nuclear power plant job duty groups, security personnel are typically deployed in a configuration in which some members of the security force have very infrequent contact with

other members or with 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, and 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 after 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 are the same individuals who are subject to the work hour requirements in this section.

Section 26.205(b) [Calculating work hours] specifies the time periods that licensees shall include when calculating the work hours of the individuals listed in § 26.205(a) for the purposes of this subpart. This requirement replaces, with editorial and substantive modifications, the requirements presented in § 26.199(b) of the proposed rule. The editorial changes are renumbering and reorganization of the requirements for clarity. The substantive change is the deletion of the provisions concerning the calculation of collective work hours as a conforming change resulting from the deletion of the collective work hour controls as described with respect to § 26.205(d)(3).

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 rule defines work hours and requirements for calculating them, as well as certain specific periods that may be excluded from the calculation to ensure consistent implementation of the work hour controls established in § 26.205(d) [Work hour controls].

The rule requires licensees to calculate work hours as the amount of time that an individual performs duties for a licensee, including all within-shift break times and rest periods during which there are no reasonable opportunities or accommodations appropriate for restorative sleep. The rule also details the periods excluded from the calculation.

The rule specifically does not limit 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 does require licensees to include hours during which an individual performs duties for the licensee. The rule defines hours worked in this broad manner because the NRC is aware that some licensees permit individuals to perform duties on behalf of the licensee from offsite 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 sleep are reduced. Many licensees operate multiple sites and at times send personnel to other sites for short periods to fill in or to extend expertise. This time away from their normal duty site must be included when calculating work hours. If the rule limited the calculation of work hours to only

those hours that an individual is paid by the licensee, works on shift, works on site, and/or is scheduled to be working by the licensee, many individuals may continue to be permitted to work excessive hours, thereby becoming fatigued. Therefore, § 26.205(b) [Calculating work hours] requires licensees to include these work hours in their work hour calculations.

Section 26.205(b)(1) [shift turnover] excludes the time periods during which an individual participates in shift turnover from the calculation of the individual's work hours. Section 26.199(b)(1) of the proposed rule defined the specific shift turnover activities that licensees may exclude from their work hour calculations. The final rule defines 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 workday, 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 the preamble to the proposed rule highlighted the importance of this activity for communicating plant status information between work crews and expressed 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 concluded 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 exclusion of shift turnover from work hour calculations is consistent with current requirements in most licensee technical specifications for the control of work hours for

personnel performing safety-related functions and with GL 82-12, “Nuclear Power Plant Staff Working Hours,” dated June 15, 1982. 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, Attachment 1, Table 2). However, the final rule more clearly describes the activities that may be included in turnover and the activities that may not be included. This provision addresses the NRC concerns arising from observations that some licensees have occasionally excluded 2 or more hours from calculated work hours on the basis that the individuals were engaged in “turnover.” To ensure that turnover is not hurried, the rule does 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 rule reduces the potential for individuals and/or licensees to use the shift turnover exclusion to perform other work activities.

Section 26.205(b)(2) [Within shift break and rest periods] permits licensees to exclude within-shift breaks and rest periods from their work hour calculations if the individual has both a reasonable opportunity and accommodations for restorative sleep. The rule permits 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 exclusion allows workers to 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 exclusion also permits 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 exclusion is limited to that portion of a break or rest period that provides a reasonable opportunity for restorative sleep. For example, a 15-minute coffee break would not provide a reasonable opportunity for restorative sleep. The rule limits the exclusion to the amount of time the individual has available to actually sleep and does 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 final rule also requires that individuals must have reasonable accommodations available 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 (e.g., bed, recliner) in a darkened, quiet room (Priest, 2000).

The degree of specificity in this section is necessary because some licensees currently 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. The discussion of § 26.205(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 rule requires licensees to include short breaks in the calculation of work hours.

Section 26.205(b)(3) [Beginning or resuming duties subject to work hour controls] permits licensees to assign individuals, who are qualified to perform the duties listed in § 26.4(a), to duties other than those listed § 26.4(a), without controlling their work hours in accordance with the work hour controls contained in § 26.205(d)[Work hour controls]. However, if these individuals are assigned or returned to performing any duties that are listed in § 26.4(a) during the calculation period, the rule requires the licensee to include all of the hours that they worked when calculating their work hours and to subject the individual to the work hour controls in § 26.205(d). For example, if a licensed operator was assigned to training for an entire calculation period, then his or her work hours would not be subject to § 26.205(d) for that period because he or she would not be performing any of the duties listed in § 26.4(a). However, if the same individual were assigned to training for only a portion of the calculation period and performed the duties listed in § 26.4(a) during the remainder of the calculation 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 as if the individual were performing operations duties for the entire calculation 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 § 26.4(a) during the calculation 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 § 26.4(a).

Section 26.205(b)(4) [Unannounced emergency preparedness exercise and drills] allows licensees to exclude certain time associated with unannounced emergency preparedness exercises and drills from the calculation of an individual's work hours. Only the time an individual works unscheduled work hours for the purpose of participating in the actual conduct of an unannounced emergency preparedness exercise or drill can be excluded. This exclusion is incorporated in the final rule in response to stakeholder comments that adjusting work schedules in anticipation of an unscheduled exercise or drill would negate the element of surprise for the individuals. The nature of such drills is that they are relatively infrequent and short in duration. Therefore, they would not have a major impact on individual fatigue and any impact would be offset by the potential contribution to safety.

Section 26.205(b)(5) [Incidental duties performed off site] allows licensees to exclude from the calculation of an individual's work hours unscheduled work performed off site (e.g., technical assistance provided by telephone from an individual's home) provided the total duration of the work does not exceed a nominal 30 minutes during any single break period. For the purposes of compliance with the minimum break requirements of § 26.205(d)(2) and the minimum day off requirements of § 26.205(d)(3) through (d)(5), such duties do not constitute work periods or work shifts. The final rule includes this exclusion in response to stakeholder comments regarding the necessity of obtaining expert advice or details on recent operating experience that may not have been included in a turnover and the burden that would be imposed by resetting the clock to account for the disruption in a break period. The nominal 30-minute reduction in the break period is not expected to have a detrimental impact on the individual's overall fatigue level and would be offset by the potential contribution to safety.

Proposed § 26.199(b)(2) would have established requirements for calculating the collective work hours of certain job duty groups that would have been subject to the collective

work hour limits in proposed § 26.199(f). The final rule does not include these requirements because the NRC eliminated the concept of collective work hours in the final rule, as discussed in § 26.205(d)(3) of this section-by-section analysis. Therefore, to conform with other changes in the final rule, § 26.205(b) does not include those aspects related to calculating collective work hours.

Section § 26.205(c) [Work hours scheduling] requires licensees to schedule the work hours of individuals who are subject to this section in a manner that is consistent with the objective of preventing impairment from fatigue resulting from the duration, frequency, or sequencing of successive shifts. This section retains the requirement presented in § 26.199(c) of the proposed rule. The NRC intends for the maximum work hour and minimum break and day off requirements specified in § 26.205(d) [Work hour controls] to apply to infrequent, temporary circumstances and not be considered guidelines or limits for routine work scheduling. In addition, the work hour controls in § 26.205(d) do 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, § 26.205(c) requires licensees to schedule personnel consistent with preventing impairment from fatigue from these scheduling factors.

The rule requires 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. Section IV.D also discusses the effects of circadian rhythms on worker fatigue. The importance of these elements for fatigue management is reflected in guidelines for work scheduling, such as EPRI NP-6748 (Baker, et al., 1990), and in technical reports, such as, NUREG/CR-4248 and the Office of Technology Assessment's report, "Biological Rhythms: Implications for the Worker" (Liskowsky, 1991). For example, the EPRI guidelines address 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, § 26.205(c) establishes a non-prescriptive, performance-based requirement.

Stakeholder interactions have interpreted this requirement as a performance-based approach in that licensees' fatigue management performance could be assessed in terms of adherence to the schedules developed in response to § 26.205(c). Although the NRC had intended this requirement to be limited to the development of work schedules, the NRC acknowledges the benefit of implementing this provision as a performance-based requirement applicable to licensee control of the actual hours worked by individuals performing the duties specified in § 26.4(a)(1) through (a)(5) and adopts this interpretation for the final rule. As a consequence, this provision of the final rule requires the work hours of individuals subject to the requirements of this section to be controlled in a manner that prevents impairment from fatigue resulting from 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.

Section 26.205(d) [Work hour controls] requires licensees to establish work hour controls for individuals who are subject to the requirements of § 26.205 [Work hours]. The provision requires licensees to establish controls that limit work periods and provide for breaks that are of sufficient length to allow the individual to obtain restorative rest. This requirement replaces§ 26.199(d) of the proposed rule, with limited editorial changes.

Section 26.205(d)(1) establishes work hour limits for consecutive, rolling periods of 24 and 48 hours and 7 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 documented in Attachment 1 to SECY-01-0113. The work hour limits from GL 82-12 also were the subject of substantial stakeholder comments during the public meetings described in the preamble of the proposed rule. In developing the requirements in this section, the NRC staff considered the information gained through these stakeholder interactions.

Section 26.205(d)(1)(i) limits the number of hours that an individual may work in any 24-hour period. The section permits individuals to work no more than 16 hours in any 24-hour period. This provision retains without change the requirement in § 26.199(d)(1)(i) of the proposed rule. This limit is identical to that specified in GL 82-12. Attachment 1 to SECY-01-0113 provides the basis for this 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, nine experts who met in 1984 to develop recommendations for NUREG/CR-4248 recommended a maximum of 12 work hours per day. Therefore, in originally developing its

Policy on Worker Fatigue, the NRC had planned a 12-hour maximum limit, but revised it to 16 hours in response to practical concerns raised by the 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 final rule retains a 16-hour limit.

Although the rule permits 16-hour shifts, other work hour limits in the rule would effectively limit the number of 16-hour shifts that licensees could assign. With respect to this issue a comment was proposed by PROS and is discussed in the preamble to the proposed rule.

Section 26.205(d)(1)(ii) limits the number of hours that an individual may work in any 48-hour period. This provision retains without change the requirement presented in § 26.199(d)(1)(ii) of the proposed rule. The section permits an individual to work no more than 26 work hours in a 48-hour period; by contrast, GL 82-12 limits individuals' work hours to 24 work hours in any 48-hour period. This change accommodates the fact that most licensee sites are now routinely working 12-hour shifts, rather than 8-hour shifts, as was the case when the NRC published GL 82-12. 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 the majority of plants now routinely working 12-hour shifts, the rule increases the maximum work hours in a 48-hour period from 24 to 26 hours to decrease the burden on licensees by accommodating situations in which a worker's relief is delayed or similar circumstances. For example, a 12-hour shift worker is able to work up to 14 hours in one day and still return to work at his or her normal time the next day, but can only work 12 hours that day. In the extreme, the 26-hour limit permits an individual to work up to 16 hours one day, followed by a minimum 10-hour break, as required in § 26.205(d)(2)(i). The individual is then limited to 10 hours of work over the next 22 hours.

When developing this requirement, which effectively relaxes by 2 hours the NRC's policy guideline in GL 82-12 for the maximum hours individuals should work in 48 hours, the NRC considered: (1) the burden associated with granting a waiver for the additional 2 hours, (2) the increased stringency of the criteria for granting a waiver of the work hour limits in § 26.207 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 2 additional work hours during a 48-hour period will 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 § 26.207 are expected to substantially reduce the number of waivers that are granted, the licensee will 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, licensees commonly use waivers to exceed the 24-hours of work in any 48-hour period limit for short durations. As a result, the NRC concluded that the relaxation will principally reduce the paperwork burden, rather than increase the hours that individuals would have actually worked under the proposed rule. Accordingly, the relaxation provides a substantive reduction in burden with a limited net effect on human performance reliability.

Section 26.205(d)(1)(iii) limits the number of hours an individual may work in any 7-day period. This section retains without change the requirement presented in § 26.199(d)(1)(iii) of the proposed rule. The requirement limits an individual to working no more than 72 hours in any 7-day period. This limit is identical to the related limit specified in GL 82-12. Attachment 1 to SECY-01-0113 provides the basis for this limit, which is summarized in this section. In the

absence of the break and day off requirements in §26.205(d)(2) and (d)(3), respectively, the limit would 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 its 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 rule codifies this expectation, in part, through § 26.205(d)(3), which requires licensees to ensure a minimum number of days off per week, averaged over a shift cycle, for individuals who are subject to the work hour controls. The rule effectively prevents an individual from consistently working six 12-hour shifts in a week.

Section 26.205(d)(2) requires licensees to provide adequate rest breaks for individuals who are performing the duties listed in § 26.4(a). This section contains, with substantial revisions, the requirements presented in § 26.199(d)(2) of the proposed rule. Although § 26.205(d)(2) retains without change the requirement presented in proposed rule § 26.199(d)(2)(i) for a 10-hour break, the final rule revises the 24-hour break requirement proposed in § 26.199(d)(2)(ii) and replaces the 48-hour break requirement proposed in § 26.199(d)(2)(iii) with an alternative break requirement. The following section-by-section discussion of § 26.205(d)(2) and (d)(3) provides a rationale for these specific changes.

Section 26.205(d)(2) is necessary to ensure that licensees provide individuals with sufficient time off between work periods (shifts) to permit them 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)).

Section 26.205(d)(2) defines 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, individuals would not perform work-related duties during rest breaks 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, not as break time, because the individual would be performing duties on behalf of the licensee while on site.

Section § 26.205(d)(2)(i) requires licensees to provide a 10-hour break between successive work periods, but permits 8-hour breaks in limited circumstances in which a shorter break is 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. Section 26.205(d)(2)(i) increases the minimum break period from 8 hours to 10 hours to provide greater assurance that individuals have an

adequate opportunity to obtain the 7–8 hours of sleep that is 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 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 ensures that individuals generally have 7 hours available each day for sleep, which is close to the 7–8 hours of sleep needed by adults in the United States (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 when sleep is restricted to 5 hours per day. Dinges, et al., 1997, and Belenky, et al., 2003, who have headed 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, when 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 7 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). An EPRI/NEI Work Hours Task Force white paper, "Managing Fatigue in the Nuclear Energy Industry: Challenges and Opportunities" (ADAMS Accession No. ML0221740179), also notes the importance of providing an opportunity for at least 8 hours of sleep. 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 10-hour break requirement provides adequate opportunity for rest when used infrequently, as is expected given other requirements in this rule. For example, § 26.205(d)(1)(ii) limits 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 is sufficient to assure adequate rest during infrequent circumstances in which individuals work extended hours (e.g., more hours than their typical 8-,10-, or 12-hour shift) and that rest opportunities will typically vary between 12 and 16 hours in duration.

The minimum 10-hour break duration also accommodates most scheduling circumstances for the common shift durations that are currently in use in the industry. A notable exception is that the 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 appropriately prevents 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.

Section 26.205(d)(2)(i) permits licensees to schedule a minimum 8-hour break in only one circumstance: if the 8-hour break is necessary to accommodate a crew's scheduled transition between work schedules. During the public meetings described in the preamble of the proposed rule, the NRC received comments that a 10-hour break requirement would occasionally interfere with a transition from 12-hour shifts to 8-hour shifts. This transition typically occurs 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 exception provides individuals with less time for recovery, the shorter break is limited to one break occurring on a very restricted frequency. Therefore, the permission for an 8-hour break for the specific circumstances of a shift transition provides scheduling flexibility with minimal potential to adversely affect an individual's ability to safely and competently perform his or her duties.

Section 26.205(d)(2)(ii) replaces and revises § 26.199(d)(2)(ii) of the proposed rule which would have required a minimum 24-hour break in any rolling 7-day period. Section 26.205(d)(2)(ii) of the final rule requires a minimum 34-hour break in any rolling 9-day period. This provision requires a periodic long duration break thereby preventing an excessive number of consecutive work shifts that would not otherwise be prevented by the requirements of § 26.205 of this rule.

Break periods longer than the minimum 10 hours between shifts required by § 26.205(d)(2)(i) 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 2-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). Recent changes in the DOT regulations for the work hours of commercial truck drivers also reflect the need for longer breaks to mitigate fatigue. 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 Parts 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.

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

§ 26.205(d)(2)(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 in 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 2-week period, including the performance of subjects who were permitted 6- and 8-hour sleep periods.

Section 26.199(d)(2)(ii) of the proposed rule would have established a requirement for a minimum 24-hour break in any 7-day period. The NRC revised the maximum number of days between the breaks in response to stakeholder comments that the proposed requirement would have substantially reduced licensee flexibility in scheduling 8-hour shifts. Stakeholders noted that many licensees currently use 8-hour schedules that include periods of 7 consecutive days. In revising the proposed requirement, the NRC considered that, although the final rule allows more consecutive days for 8-hour and 10-hour shifts, the final rule allows licensees the flexibility to more readily optimize 8-hour shift schedules to minimize the transitions between day, evening, and night shifts that can lead to worker fatigue. Although this relaxation also allows more consecutive shifts for individuals on 10-hour shifts, individuals on 10-hour shifts typically

do not work a rotating schedule and thereby do not experience the disruption of their circadian cycle that exacerbates the cumulative fatigue effects of consecutive work shifts. The final rule also provides flexibility to accommodate other practical considerations such as scheduling training on a Monday through Friday basis and allows a contingency day in 8-hour shift schedules that includes a series of seven consecutive 8-hour shifts as part of the routine shift cycle.

The final rule also revises the minimum duration of the break period from 24 hours, as specified in § 26.199(d)(2)(ii) of the proposed rule, to a minimum 34-hour break. The revision more clearly states the NRC's intent to require a periodic "day off" in which individuals have the opportunity for two consecutive sleep periods without an intervening work period. The 34-hour break duration provides opportunity for two consecutive sleep periods without an intervening work period, supports use of forward rotating and fixed shifts, and allows for the possibility that individuals may work 26 hours in a 48-hour period contiguous to the break.

Given these considerations, the NRC concluded that § 26.205(d)(2)(ii) of the final rule provides a level of assurance of worker FFD relative to fatigue that is comparable to that which would have been achieved through the requirement in § 26.199(d)(2)(ii) of the proposed rule. The provision for a 34-hour break in any rolling 9-day period serves both to prevent and mitigate cumulative fatigue. The 34-hour break periods will 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.

Section 26.205(d)(2) of the final rule does not retain the requirement for a minimum 48-hour break in any rolling 14-day period as would have been required by § 26.199(d)(2)(iii) of the

proposed rule. The NRC received many stakeholder comments in opposition to the 48-hour break requirement. One commenter stated that fixed break requirements and collective work hour restrictions will lead to significant safety implications and could affect a licensee's ability to restore inoperable equipment in a timely manner. This view was echoed by many other commenters. Another commenter found fault with focusing on days off without considering the number of hours worked in a particular day and the breaks between work periods. In addition, many commenters raised the issue of work schedule disruption as a result of the 48-hour break requirement. They asserted that, for workers on the night shift, having one day off provides an additional rest period and allows the worker to maintain a consistent pattern of work and sleep habits, which reduces the risk of accidents on the job. Two days off, however, may interfere with his or her sleep cycle, and as a result, the individual would have to readjust to the night shift after the 2-day break. According to the commenters, some workers have stated that having 2 days off is worse than having no days off. They also argued that a 1-day break in any 7-day period is more than adequate when combined with other rule provisions to address cumulative fatigue. Thus, commenters requested that the 48-hour break requirement during outage periods be deleted.

In response to stakeholder comments, the NRC replaced the requirement proposed in § 26.199(d)(2)(iii) with alternative requirements that ensure that each worker receives a minimum number of days off per week, on average, while the plant is operating or receives a minimum number of days off in each consecutive 15-day period of a plant outage. Security personnel subject to the requirements of § 26.205 are also subject to requirements for minimum days off in 15-day periods during security system outages and increased threat conditions. These alternative extended break requirements are in § 26.205(d)(3) through (d)(5) of the final rule and are addressed in the section-by-section analysis applicable to those requirements. In adopting the alternative requirement for the final rule, the NRC considered

that, whereas the alternative requirements assured that workers subject to the requirement would receive a minimum number of days off, which would serve to limit the potential for cumulative fatigue, the requirements would not assure that any of the days off would be consecutive, as would have been required by the minimum 48-hour break requirement of proposed § 26.199(d)(2)(iii). In proposing the 48-hour break requirement, the NRC cited several studies that demonstrate the benefits of consecutive days off, noting that one night of unrestricted sleep is not sufficient to fully recover from the cumulative fatigue that can result from restricted sleep and extended work hours. However, the NRC also considered that the minimum day off requirements would, in effect, limit each individual's average number of work hours and the average number of consecutive work shifts between days off, thereby reducing the potential for cumulative fatigue. As a consequence, the final rule's requirements reduce the need for consecutive days off to prevent or mitigate fatigue. The NRC also expects that common scheduling constraints and worker preferences will cause licensees to schedule days off in succession. In addition, the NRC considered that the alternative requirements of § 26.205(d)(3) and (d)(4) of the final rule provides licensees greater flexibility in meeting scheduling demands and minimizing circadian disruption for workers.

Section 26.205(d)(3) requires individuals subject to the requirements of § 26.205 to have a minimum average number of days off per week. The specific number of days off depends upon the length of shifts in the work schedule of the individual. This requirement replaces the requirements presented in proposed § 26.199(f) [Collective work hour limits], which would have required licensees to control the collective work hours of each group of individuals performing the duties subject to the work hour requirements and ensure that the collective work hours of each job duty group would not have exceeded an average of 48 hours per person per week in any averaging period. Section 26.205(d)(3), by requiring a minimum number of days off, indirectly limits average weekly work hours to levels comparable to those

that would have been permitted by the collective work hour limits of the proposed rule. Consequently, § 26.205(d)(3) of the final rule performs the same function as the requirements of proposed § 26.199(f), providing reasonable assurance that the FFD of individuals subject to the work hour requirements is not impaired by cumulative fatigue. As described with respect to § 26.205(d)(2), this requirement also addresses an objective of the 48-hour break requirement of the proposed rule by limiting the potential for the cumulative fatigue of individuals while the plant is operating. The provision does not require that days off be provided consecutively, as would have been required by proposed § 26.199(d)(2)(iii), but rather allows licensees discretion, within the constraints of the other work hour limit and break requirements, in distributing days off throughout the shift cycle. As a consequence, § 26.205(d)(3), like proposed § 26.199(d)(2)(iii), is intended to ensure that individuals receive sufficient days off on a periodic basis to prevent cumulative fatigue.

The minimum day off requirements of § 26.205(d)(3) will ensure that licensees manage during periods of normal plant operation the potential for cumulative fatigue (i.e., fatigue from successive weeks 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 requirements prevent excessive use of the maximum work hours and minimum rest breaks that are permitted under § 26.205(d)(1) and (d)(2). In addition, proactively controlling work hours to ensure individuals receive a minimum weekly average number of days off while the plant is operating is likely to reduce the need for licensees to grant waivers of the work hour requirements in § 26.205(d)(1) and (d)(2). Individuals will be better rested and less susceptible to cumulative fatigue from the increased work hours that are common during outages and that are necessary to augment security staffing during increased threat conditions. Therefore, the minimum day off requirement is essential for limiting cumulative fatigue and augments other important elements of licensees' fatigue management programs.

Requiring a minimum number of days off that results in a maximum average work week of approximately 48–54 hours per week helps to ensure that licensees meet a fundamental objective of the NRC's Policy on Worker Fatigue. The Policy, promulgated in 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. Section 26.205(d)(3) establishes requirements that are expected to result in maximum average work weeks in the range of 48–54 hours, thereby ensuring that work hours approaching the limits in § 26.205(d)(1) and NRC's Policy on Worker Fatigue are the exception and not routine.

The minimum day off requirements of § 26.205(d)(3) also address, in part, the cumulative fatigue concerns reported by security personnel in the months following the terrorist attacks of September 11, 2001. 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 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 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 comments regarding differences among individuals in their abilities and desires to work overtime. The proposed rule would have permitted a group of workers who perform similar duties to average 48 hours of work over a period not to exceed 13 weeks. Because the proposed limit would have been imposed on a job duty group's average number of work hours during an averaging period, licensees would have been able to distribute overtime among their workers based on their assessment of individuals' abilities and desires to work overtime. Stakeholder comments on the proposed requirement for collective work hour controls raised several concerns.

Some stakeholders expressed the concern that the collective work hour controls were not an effective means for addressing fatigue. One stakeholder expressed the concern that the collective work hour controls would allow licensees to force individuals to work overtime. Another stakeholder expressed the opinion that collective work hour controls are not an effective means to address the known physiological fatigue risks contributed by individual operators. Other stakeholders expressed the concern that licensees may be able to manipulate the collective work hour calculations. Other commenters asserted that the collective work hour controls were unnecessary to mitigate the effects of cumulative fatigue and that the controls would limit the flexibility to increase work hours in a job-duty group based on operational needs. These commenters stated that other rule provisions, such as the work schedule, individual work hour limits, and individual break requirements, as well as the provisions concerning fatigue assessments and the self-declaration process adequately address cumulative fatigue.

Although the NRC acknowledges that Subpart I provisions concerning fatigue assessment and self-declaration are important for the detection of cumulative fatigue, these provisions, like the individual work hour limit and break requirements of the proposed rule, do not adequately address the prevention of cumulative fatigue. Accordingly, the final rule

addresses the comments on the limitations of the collective work hour requirements by replacing the requirements of § 26.199(f) of the proposed rule with the minimum day off requirements in § 26.205(d)(3) of the final rule. The minimum day off requirements were largely derived from a work hour control proposal submitted by NEI as a comment on the proposed rulemaking. Although in several instances the NRC did not adopt the specific minimum number of days off that NEI proposed in its comments, § 26.205(d)(3) establishes requirements similar to those proposed by NEI by requiring each individual subject to the requirements of § 26.205 to have a minimum average numbers of days off per week.

Section 26.205(d)(3) defines, for the purposes of Subpart I, the term *day off* as a calendar day in which an individual does not start a work shift. The definition ensures consistent licensee implementation of the requirements in § 26.205(d)(3). In developing the definition, the NRC considered the alternative of defining the requirements of § 26.205(d)(3) in terms of 24-hour break periods. A stakeholder at the March 29, 2006, public meeting concerning this rulemaking noted that the number of 24-hour breaks in a schedule could be readily influenced by the number of rotations between shifts and therefore could encourage scheduling practices that achieved compliance with the requirement through schedules that were adverse to the circadian adjustment of workers. As defined in the final rule, use of the term *day off* does not encourage such adverse scheduling practices and results in requirements that establish uniform limits for all schedule designs. In addition, the definition enables workers and schedulers to readily determine the number of days off in a schedule without the need to calculate the duration of break periods.

Section 26.205(d)(3)(i) through (d)(3)(iv) specifies the minimum number of days off for each individual subject to the requirements of § 26.205 in terms of a minimum number of days off per week, averaged over the shift cycle. The requirements in this section thereby allow the number of days off for an individual to vary from week to week, but mandate that over the

duration of the shift cycle, the average number of days off per week meets the specified minimum. Section 26.205(d)(3) requires that, for the purposes of calculating the average number of days off required in this section, the duration of a shift cycle may not exceed 6 weeks. This maximum duration of a shift cycle limits the period over which licensees are permitted to average the number of days off and thereby limits the potential for cumulative fatigue by preventing an excessive number of consecutive weeks in which individuals may be working the maximum hours allowed by § 26.205(d)(1) while having only the minimum breaks required by § 26.205(d)(2). The 6-week maximum for shift cycles also corresponds to the longest shift cycle commonly used in the U.S. nuclear industry.

Section 26.205(d)(3)(i) requires individuals who are working 8-hour shift schedules to have at least 1 day off per week, averaged over the shift cycle. This minimum day off requirement allows an average of 48 hours of work per week, assuming individuals receive the minimum number of days off with no work shifts extended beyond 8 hours. This requirement is therefore generally consistent with the 48-hour collective work hour requirement of § 26.199(f) of the proposed rule, though it imposes the requirement on an individual rather than a group basis. This requirement is also consistent with the NEI proposal for an average of 1 day off per week, averaged over a shift cycle, for predominantly 8-hour shift schedules.

In developing requirements to address cumulative fatigue, the NRC considered several types and sources of information, including (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.

EPRI NP-6748 (Baker, et al., 1990) and NUREG/CR-4248 are two of the most comprehensive documents on worker fatigue in the U.S. nuclear industry. Like the collective

work hour limits of the proposed rule, the minimum average number of day off requirement is a new concept developed to meet the rule's objectives while also addressing stakeholders' unique circumstances and specific concerns. 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 this 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 overtime use 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, noting that this individual maximum on overtime should not be a group norm. Work schedules that meet the minimum day off requirements will result in levels of individual work hours that are typically in the middle of the range of work hours defined by the maximum routine scheduling limits and maximum individual overtime. 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 also 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. A survey of nuclear power plant personnel in the United Kingdom yielded similar results.

A minimum day off requirement will limit individuals to approximately 400 to 500 hours of overtime in a year. Therefore, the minimum day off requirements permit levels of overtime while the plant is operating that are at the upper extreme of the number of overtime hours for which nuclear power plant personnel have expressed a tolerance. In addition, the minimum day off requirements are less restrictive than the limit implied by worker opinions because the minimum day off requirements of § 26.205(d)(3) would not apply during the first 60 days of plant outages, and for security personnel, during the first 60 days of plant outages, security system outages, or increased threat conditions.

Together with 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 less. The NRC also reviewed work hours data collected by NEI (ADAMS Accession No. ML003746495) and found that, although individual sites varied substantially, 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 approximately 48 hours is an achievable objective for operations personnel as well, although it was not a current practice at a small fraction of nuclear power plants.

The minimum day off requirements are comparable to, though less restrictive than, limits on workers in other industries within the United States and the limits imposed by other countries that regulate overtime for nuclear power plant workers. The NRC staff noted that several other countries address cumulative fatigue of nuclear power plant personnel 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 minimum day off requirements because they directly limit hours of work, rather than work days, and permit fewer hours of work (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 United States.

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.”

Moreover, the amount of overtime permitted by the minimum day off requirements would be greater than the amount used in most continuous operations. Circadian Technologies, Inc., a consulting firm that is expert in fatigue management, regularly surveys U.S. and Canadian companies conducting 24/7 operations. Its 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, Inc., 2000). Circadian Technologies, Inc., noted

that the average overtime for workers in extended operations in the United States was 12.6 percent above the standard work week in the first 8 months of 2003, with utilities averaging 14.9 percent (Circadian Technologies, Inc., 2003).

Therefore, the minimum day off requirements establish appropriate limits on work schedules while the plant is operating. The requirements would ensure that individuals subject to the work hour requirements of § 26.205 have sufficient days off to prevent fatigue. The minimum day off requirements will indirectly permit levels of overtime at the upper extreme desired by most nuclear power plant workers while limiting overtime to levels comparable to those recommended by work scheduling and fatigue experts.

Section 26.205(d)(3)(ii) requires that individuals who are working 10-hour shift schedules have at least 2 days off per week, averaged over a shift cycle. Individuals working schedules that meet the minimum day off requirements of this section would therefore be working, on average, five 10-hour shifts (50 hours) per week. In developing this requirement the NRC considered the NEI proposal for a minimum of 1 day off per week average for 10-hour shift schedules. The NRC concluded that such a limit would allow excessive work hours (i.e., an average of 60 hours per week) for routine scheduling, thus creating the potential for cumulative fatigue. The NRC would not expect such a limit for long-term work hour control to prevent fatigue concerns such as those reported by security personnel working on the order of 60 hours per week in the months following the terrorist attacks of September 11, 2001. The section-by-section analysis for § 26.205(d)(3)(i) addresses in detail the basis for minimum day off requirements that effectively limit work schedules to work weeks averaging approximately 48 hours per week. Section § 26.205(d)(3)(i) would permit an average work schedule of approximately 50 hours. Although this requirement for 10-hour schedules would allow 2 more hours per week than the requirement for 8-hour schedules, 10-hour schedules are not typically used for rotating shift schedules. As a consequence, the individuals on those schedules are

less likely to experience the disruption of their circadian cycles that is caused by rotating shifts and therefore better able to cope with the additional work hours.

Section 26.205(d)(3)(iii) requires that individuals performing the duties described in § 26.4(a)(1) through (a)(4) have at least 2.5 days off per week averaged over a shift cycle. In developing this requirement, the NRC considered NEI's proposal to require a minimum of 2 days off per week for all individuals working 12-hour shifts subject to the work hour requirements, except security personnel. The NRC judged 2 days off per week to be insufficient for routine scheduling of 12-hour shifts because it would allow an average work week of 60 hours, which the NRC expects would lead to cumulative fatigue. Furthermore, such a requirement would ensure substantially fewer days off than would be recommended by the scheduling guidelines contained in EPRI NP-6748 (Baker, et al., 1990) and NUREG/CR-4248.

In developing § 26.205(d)(3)(iii), the NRC also considered the effect of scheduled training weeks on the overall work hours of operations personnel. Operators have 1 week of requalification training in most shift cycles. The training week typically consists of four 9-hour days or five 8-hour days. As a consequence, § 26.205(d)(3)(iii) has the effect of limiting covered operations personnel to an average work week ranging from 48.8 hours to 52 hours, in most shift cycles (i.e., when the shift cycle contains a training week). The specific number of hours depends on the number of weeks in the shift cycle and the training week schedule. This estimate also assumes that individuals do not work longer than their scheduled 12-hour shift.

The effect of § 26.205(d)(3)(iii) for personnel working 12-hour shifts who perform the maintenance, chemistry, health physics, and fire brigade duties that are subject to the work hour requirements of § 26.205(d) is a maximum average work week of 54 hours, assuming minimum days off with no shifts longer than 12 hours. The NRC recognizes that the maximum average work week for individuals working 12-hour shifts while performing the duties in § 26.4(a)(2) through (a)(4) is greater than that for operations personnel performing 12-hour

shifts. However, the duties described in § 26.4(a)(2) through (a)(4) involve fewer and less prolonged periods of sedentary activities, which can contribute to degraded alertness, and monitoring activities, which are particularly susceptible to degraded vigilance. As a consequence the NRC considers these differences that may result among the schedules for personnel performing the operations duties described in § 26.4(a)(1) and personnel performing the duties described in § 26.4(a)(2) through (a)(4) to be acceptable and appropriate for fatigue management when considered in the context of the other requirements of this subpart.

Section 26.205(d)(3)(iv) of the rule requires that licensees ensure that individuals who are working 12-hour shifts and performing the security duties described in § 26.4(a)(5) have a minimum of 3 days off per week, averaged over a shift cycle. This requirement limits the security personnel who are subject to this requirement to an average work week of 48 hours. In developing this requirement the NRC considered the technical basis described with respect to § 26.205(d)(3) and public comment on the collective work hour controls of the proposed rule. The NRC also considered its experience with implementing the group work hour controls that were required for security personnel by the compensatory measures of order EA-03-038. The NRC has generally found that licensees have implemented work hour controls consistent with the requirements of the compensatory measures. However, the NRC has received a limited number of concerns from security personnel stating that they are still experiencing excessive fatigue leading to the perception that the requirements have not been fully protective of all security personnel. The NRC also notes that it has received numerous reports of inattentive security personnel at U.S. nuclear power plants within the last 2 years. In addition, the NRC considered the critical importance of mental alertness and maintaining vigilance to the effective performance of security personnel and the unique challenges of security duties and work environments to meeting these needs (see the section-by-section analysis of § 26.205(a) for a more detailed discussion of the relationship between security duties and fatigue). Given these

considerations, the NRC concluded that it is appropriate to establish more stringent work hour requirements for security personnel than other individuals subject to the requirements of § 26.205. Accordingly, § 26.205(d)(3)(iv) requires a minimum of 3 days off per week, averaged over a shift cycle, for individuals working 12-hour shifts who are performing the security duties described in § 26.4(a)(5).

Section 26.205(d)(4) excludes the first 60 days of unit outages from the minimum day off requirements in § 26.205(d)(3) for individuals performing the duties specified in § 26.4(a)(1) through (a)(4) (i.e., certain operations, maintenance, chemistry, health physics, and fire brigade personnel). During the first 60 days of a unit outage, § 26.205(d)(4) requires licensees to ensure that these individuals have a minimum of 3 days off in each successive (i.e., non-rolling) 15-day period. After the first 60 days of a unit outage, these individuals are again subject to the minimum day off requirements of § 26.205(d)(3), except as permitted by § 26.205(d)(6).

The minimum day off requirements in § 26.205(d)(3) address the long-term control of work hours while permitting the occasional use of extended work hours for short duration circumstances such as equipment failure, personnel illness, or attrition. The requirements in § 26.205(d)(4) address the control of work hours for unique plant conditions (i.e., unit outages) which require extended work hours for a more sustained period of time. In developing the minimum day off requirements of § 26.205(d)(4), the NRC considered several factors, including current policy, the bases for the policy, lessons learned from the policy implementation, and public comment on the proposed rule.

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 maximum duration of the exclusion period, the NRC considered that, by the end of 60 days of work at the limits permitted by § 26.205(d)(1) and (d)(2), individuals who are performing the duties specified in § 26.4(a)(1) through (a)(4) will have (1) worked 576 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 represents a 60-percent reduction in the time available to recover and prevent cumulative fatigue. Further, with each passing week of 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 unit outages in determining whether the cost to licensees imposed by limiting the exclusion period to 60 days is 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. Many comments on the proposed rule recommended that the 8-week exclusion period be increased to a 10-week exclusion period. This increase in the exclusion period would substantially increase the period of time that an individual would be working with reduced recovery time. During the exclusion period, individuals are permitted to work up to 72 hours in a 7-day period and are assured of just 3 days off in each 15-day period. Individuals who work 12-hour shifts, which is common during outages, will average up to 67.2 hours per week, which represents 160 percent of their normally scheduled hours with less than half of their normally scheduled days off for recovery, for a period of up to 2 months. Extending the outage exclusion period to prolong these conditions would substantively increase the potential for cumulative fatigue and fatigue-related personnel errors. Therefore, the NRC did not adopt the recommendation to increase the duration of the exclusion period in the final rule.

The NRC also received several comments on the proposed rule which recommended that the NRC eliminate the exclusion for outage periods. In an early phase of developing the work hour requirements in Subpart I, the NRC considered establishing a set of uniform requirements that would be applicable regardless of whether a unit was operating or shut down. However, as noted with respect to § 26.205(d)(4), the NRC recognizes that individuals are capable of working with limited rest without degraded performance for short periods of time. As

a consequence, the NRC considers it appropriate to allow flexibility within the work hour requirements to accommodate limited periods of more intensive work schedules, such as unit outages. However, the NRC limits this flexibility to infrequent circumstances, such as unit outages, to limit the potential for cumulative fatigue. Further, the NRC considered the substantial cost to licensees for meeting the requirements applicable to periods of plant operation through either increasing staffing (to minimize outage durations) or increasing outage durations to accommodate a less intensive work schedule. Given these considerations, the NRC concluded that a limited duration period of less restrictive work hour requirements, as included in the final rule, is better justified by the costs and benefits.

The 60-day exclusion period that § 26.205(d)(4) permits from the minimum day off requirements of § 26.205(d)(3) replaces the 8-week exclusion period that proposed § 26.199(f) would have permitted from the collective work hour limits. The discussion with respect to § 26.205(d)(3) presents the issues the NRC considered in deciding to replace the collective work hour limits with minimum day off requirements. The NRC revised the maximum duration of the permitted exclusion period to a duration that is comparable to the 8-week (56-day) period of the proposed rule, but better conforms with the minimum day off requirements in § 26.205(d)(4) and (d)(5). The final rule establishes minimum day off requirements in terms of 15-day periods, rather than weeks, as the proposed rule would have required. As a consequence, the NRC revised the maximum duration of the exclusion period to 60 days (4 x 15) to encompass four complete periods of time.

Section 26.205(d)(4) requires licensees to ensure that individuals performing the duties specified in § 26.4(a)(1) through (a)(4) have at least 3 days off in each successive (i.e., non-rolling) 15-day period during the first 60 days of a unit outage. This requirement replaces, in part, proposed § 26.199(d)(2)(ii), which would have required that these individuals have a minimum 24-hour break in any 7-day period. This requirement also replaces, in part, proposed

§ 26.199(d)(2)(iii), which would have required that these individuals have a minimum 48-hour break in any 14-day period, except during the first 14 days of an outage. The NRC is replacing these requirements with § 26.205(d)(4) in response to public comment (see the discussion of public comment with respect to § 26.205(d)(2)(i) and (d)(3)). The combined effect of § 26.199(d)(2)(ii) and (d)(2)(iii) of the proposed rule would have been to require 2 days off in the first 2 weeks of the outage and 3 days off in each subsequent 14-day period. Section 26.205(d)(4) establishes a requirement that is similar to, though more flexible and less complex than, the requirements it replaces.

As described with respect to § 26.205(d)(2), the NRC received many stakeholder comments on the proposed rule regarding the 48-hour break requirement. Several commenters asserted that, for workers on the night shift, having 1 day off provides an additional rest period and allows the worker to maintain a consistent pattern of work and sleep habits, which reduces the risk of accidents on the job. However, two days off may interfere with his or her sleep cycle and, as a result, the individual would have to readjust to the night shift after the 2-day break. The NRC acknowledges that these concerns may be particularly applicable during outage periods when it is common for licensees to schedule many individuals on a fixed night shift for the duration of an outage. The final rule addresses this concern by requiring a comparable number of days off, to limit the potential for cumulative fatigue, while providing licensees increased flexibility in the distribution of the days off. As a consequence, licensees may schedule single days off to limit circadian disruption for workers on the night shift. Alternatively, they may provide the days off in consolidated blocks to provide extended breaks of 2 or more consecutive unrestricted sleep periods which are important to reducing cumulative fatigue.

The objective of the requirement in § 26.205(d)(4) is to ensure that individuals performing the duties described in § 26.4(a)(1) through (a)(4) have sufficient periodic long-

duration breaks to prevent cumulative fatigue from degrading their ability to safely and competently perform their duties. The minimum day off requirement in § 26.205(d)(4) serves the same general function as the minimum day off requirements of § 26.205(d)(3). However, whereas § 26.205(d)(3) is principally applicable to extended periods while a unit is operating, § 26.205(d)(4) is applicable to periods of limited duration during unit outages. As a consequence, the specific limits and details of these requirements differ to accommodate these different plant conditions and periods of applicability.

Like the requirements of § 26.205(d)(3), the minimum day off requirements of § 26.205(d)(4) are necessary because the maximum individual work hour requirements of § 26.205(d)(1) and the minimum break requirements § 26.205(d)(2) are appropriate for limited periods, but do not preclude licensees from scheduling extended work hours for sustained periods that would result in cumulative fatigue (e.g., a series of weeks that require individuals to work six consecutive 12-hour shifts with only 1 day off).

In its development of § 26.205(d)(4), the NRC considered 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 the preamble to the proposed rule also confirmed the NRC observation that some licensees were scheduling outages with several weeks of 12-hour shifts with no scheduled days off. The NRC also considered industry comments submitted during the public comment period that asserted 1 day off in 7 is adequate for maintaining worker performance and that offering schedules that included these levels of overtime is necessary to attract supplemental outage workers.

Accordingly, the NRC expects that such scheduling practices would continue, absent any requirement to prohibit them. The minimum day off requirement of § 26.205(d)(4) is the one requirement of this final rule that prevents individuals who perform the duties listed in § 26.4(a)(1) through (a)(4) from working 72 hours per week for the entire first 8 weeks of a unit outage. In this regard, the NRC notes that the duties listed in § 26.4(a)(1) through (a)(4) are those the NRC considers most important for fatigue management because of their relationship to the protection of public health and safety. In particular, these duties include operating and maintaining systems and components that a risk-informed process has shown to be significant to public health and safety.

As described with respect to § 26.205(d)(2)(ii), break periods longer than the minimum 10 hours required by § 26.205(d)(2)(i) are necessary on a regular basis to maintain reliable human performance. A 10-hour break provides an adequate opportunity to sleep (approximately 7 hours for most individuals) only if one assumes the minimal times for meals, hygiene, and commuting, as described with respect to § 26.205(d)(2)(i), with no other daily living obligations. During unit outages, work schedules of 12-hour shifts and limited days off are common. As the ratio of 12-hour work shifts to days off increases, the pressure on individuals to restrict sleep time in order to meet daily living obligations that cannot be deferred increases. Without periodic days off, 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). Such sleep restriction will compound the effect of the long (12-hour) work shift resulting in impairment on the job.

The NRC also considered ways to prevent and mitigate cumulative fatigue in roving outage crews and other transient workers who predominantly work during plant outages in the development of this requirement. During the stakeholder meetings discussed in the preamble

to the proposed rule, many stakeholders expressed a strong desire for transient workers to be subject to work hour controls. One stakeholder observed 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.

During development of the proposed rule, the NRC staff considered establishing long-term work hour controls. However, collective work hour controls would not be effective because these individuals typically work during outages when the collective work hour controls would not be applicable or practical. The NRC staff then considered individual long-term (quarterly and yearly) work hour limits for transient workers. However, industry representatives strongly objected because these transient workers 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. As noted with respect to § 26.205(d)(4), the minimum day off requirement of this section replaces, in part, the 48-hour break requirement of the proposed rule, and is the single requirement that prevents individuals responsible for performing risk-significant duties from working extended periods of 72-hour work weeks.

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 work hour limits and break requirements applicable to unit outage periods. For these individuals, the minimum day off requirement of § 26.205(d)(4) is the single requirement that will prevent such individuals from performing risk-significant duties while

working 72 hours per week for substantial portions of a year.

In developing the minimum day off requirements for the final rule, the NRC considered scheduling practices during outages and determined that it could not practically extend the same approach used in § 26.205(d)(3) because the requirements of this section are based on shift cycles which provide a defined period to which the average day off requirement will apply. The length of outages and increased threat conditions is variable and therefore does not provide a consistent averaging period. The NRC further considered establishing a requirement of a minimum of 3 days off in any 14-day period because that would have been similar to the requirements it would have replaced. However, the NRC ultimately determined that 3 days off within a 15-day period provided licensees the flexibility to establish a schedule comprising a repeating series of 4 work shifts followed by 1 day off. As a consequence, the rule allows licensees the option to establish a schedule that is predictable, a characteristic desired by schedulers and workers, and that both mitigates and prevents cumulative fatigue by including periodic rest breaks. In conjunction with § 26.205(d)(1)(iii), this requirement prevents an excessive series of 12-hour shifts and 72-hour workweeks. Working 72 hours per week for extended periods is inconsistent with the research cited with respect to § 26.205(d)(2)(i) and (d)(2)(ii). The NRC also concluded that it is not consistent with providing reasonable assurance that individuals are fit to perform their duties.

During the development of the final rule the NRC also considered a graded approach to the minimum day off requirements for outages. Specifically, the staff considered an option which would have allowed licensees to defer 1 of the 3 required days off in a 15-day block to the subsequent 15-day block (i.e., licensees could provide individuals only 2 days off in a 15-day block but would be required to provide those individuals 4 days off in the subsequent 15-day block). This option would have required fewer days off for outages of less than 15 days and provided additional scheduling flexibility for longer outages. At the March 29, 2006 public

stakeholder meeting regarding this rulemaking the staff discussed the potential of a graded approach and solicited stakeholder comment. Only one licensee representative stated that a graded approach may provide useful flexibility. The NRC subsequently considered the increased potential for cumulative fatigue that would result from deferring days off, the increased complexity of the rule and scheduling to meet the requirements, the minimal stakeholder interest in a graded approach, and determined that the option for deferring a required day off to a subsequent 15-day block was not warranted.

Section 26.205(d)(5) requires that during the first 60 days of unit outages, security system outages, and increased threat conditions, licensees control the hours worked by individuals performing the security duties specified in §26.4(a)(5) in accordance with the requirements in § 26.205(d)(5)(i) and (d)(5)(ii). The effect of this section is to provide a 60-day exception from the minimum day off requirements in 26.205(d)(3) for these plant conditions. After the first 60 days of these periods, these individuals are again subject to the minimum day off requirements of § 26.205(d)(3), except as permitted by § 26.205(d)(6). The purpose of this exception is to allow licensees the flexibility provided by the less stringent day off requirements of § 26.205(d)(5)(i) and (d)(5)(ii) to provide the increased level of security staffing that is required by these unique circumstances. The requirements in § 26.205(d)(5)(i) and (d)(5)(ii) provide the restrictions necessary to prevent and mitigate excessive cumulative fatigue during these periods.

Section 26.205(d)(5)(i) provides an exception from the minimum day off requirements of § 26.205(d)(3) for personnel performing the duties described in § 26.4(a)(5) during unit outages or unplanned security system outage. The requirement limits this exception period to 60 days from the beginning of the outage and requires that individuals performing the security duties identified in § 26.4(a)(5) during this period have a minimum of 4 days off in each non-rolling 15-day period. This requirement replaces the collective work hour limit of 60 work hours per

person per week that § 26.199(f)(2)(i) of the proposed rule would have required for these individuals during the first 8 weeks of a unit outage or a planned security system outage.

Section 26.205(d)(5) permits licensees to meet the minimum day off requirements of § 26.205(d)(5)(i) as an exception to the more stringent minimum day off requirements in § 26.205(d)(3). The rule permits this exception for a limited duration, 60 days to accommodate the short-term demand for increased work hours associated with these outages while limiting cumulative fatigue. Therefore, the requirement provides reasonable assurance that security personnel will 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 limiting the duration of the exception from the requirements of § 26.205(d)(3) during unit outages is described with respect to § 26.205(d)(4). In addition to establishing a minimum day off requirement for personnel performing the security duties identified in § 26.4(a)(5) during the first 60 days of a unit outage, § 26.205(d)(5) establishes minimum day off requirements for these individuals for the first 60 days of a planned security system outage. Planned security system outages are typically of very short duration relative to unit outages and the NRC does not expect that planned security system outages will exceed 60 days. However, the rule establishes the 60-day limit for planned security system outages 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 perform their duties safely and competently during these outage and increased threat conditions is based on the length of time individuals work additional hours, not on the nature of the site condition.

Section 26.205(d)(5)(i) replaces, in part, the requirements limiting work hours of security personnel established by order EA-03-038 with alternative requirements that will achieve the same objective. Collectively, the requirements in Subpart I more effectively achieve the

objectives of the compensatory measures and therefore the NRC intends to revoke order EA-03-038 following implementation of this rule. This requirement limits, with the exception specified in § 26.205(d)(6), the maximum duration of the outage requirements to 60 days instead of the 120-day period order EA-03-038 permits.

Since September 11, 2001, the NRC has received several 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 as a result of the post-September 11 threat environment. The nuclear security officers questioned their readiness and ability to perform their required job duties because of 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 requires 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 need for periodic long breaks was discussed with respect to § 26.205(d)(2) and (d)(3). 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 increased work hours 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 would also provide more flexibility. The 60-hour limit of the proposed rule would have ensured 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.

As discussed with respect to § 26.205(d)(3), stakeholder comments on the proposed rule expressed a range of concerns regarding the need for, and effectiveness of, collective work hour controls. As a consequence, the NRC replaced the collective work hour limits of the proposed rule with the minimum day off requirements outlined in § 26.205(d)(3) through (d)(5). More specifically, the requirement for a minimum of 4 days off in each 15-day period of the first 60 days of an outage required in § 26.205(d)(5)(i) establishes a requirement in the final rule that is comparable to the 60-hour collective work hour limit of the proposed rule, while addressing stakeholder comments regarding the importance of addressing worker fatigue on an individual basis. Although § 26.205(d)(5)(i) does not directly limit work hours, the requirement has the effect of limiting individuals to an average work week of 61.6 hours, assuming no work shifts exceed 12 hours. The NRC established the minimum day off requirement in terms of 15-day periods to establish requirements for security personnel in time periods consistent with the minimum day off requirements for other personnel to simplify licensee implementation of the requirements of this section.

For several reasons, control of work hours for security personnel must be more stringent

than for other individuals who are subject to the 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 in which some members of the security force have very infrequent contact with other members of the security force or with other plant personnel. A lack of social interaction 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.

Consistent with the requirements of the proposed rule, the final rule requirement differs from that in Order EA-03-038 by establishing more stringent work hour requirements for unplanned plant outages than for increased threat conditions. Order EA-03-038 currently does not impose collective work hour limits for unplanned plant outages. As discussed in the preceding paragraph, security duties are particularly susceptible to fatigue. Therefore, the NRC considers that the minimum day off requirement 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 plant outages, although licensees would be unable to

sufficiently plan for the increased security demands that typically accompany plant outages, licensees can control the demands on the work hours of security personnel by controlling the outage activities (e.g., maintenance) that create the increased demand for security personnel. As a consequence, work hours that may compromise the FFD of security personnel, such as those that would be permitted in the absence of the minimum day off requirements of § 26.205(d)(5)(i), cannot be justified. The economic benefit gained by licensees cannot justify the increased potential for fatigue-induced errors.

Section 26.205(d)(5)(ii) provides an exception from the minimum day off requirements for security personnel for the first 60 days of an unplanned security system outage or an increased threat condition. This requirement replaces proposed § 26.199(f)(2)(iii), which would have provided 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 exception allowed by § 26.205(d)(5)(ii) is consistent with 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 of up to 120 days. Section § 26.205(d)(5)(ii) establishes 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 fatigue management requirements, including the work hours controls in § 26.205(d)(1) and (d)(2), provide reasonable assurance of guard readiness during the exception period. Therefore, the benefit to plant security of ensuring adequate staffing during such unplanned conditions outweighs the potential for excessive worker fatigue.

Staffing to a level necessary to meet the minimum day off requirements of § 26.205(d)(3) during unplanned security system outages or increased threat conditions would not be practical because it would require licensees to maintain security staffing in numbers that would be excessive for the vast majority of circumstances. Limiting periods of extended work hours for security personnel to 60 days aligns the exception period for security personnel with the exception period for other personnel subject to the work hour requirements, 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 60 days. Outages of this duration have been uncommon. Therefore, reducing the exclusion period from 120 days to 60 days is not likely to have a practical impact on licensees.

The Department of Homeland Security has refined its threat system to compartmentalize increases in threat conditions for individual business sectors and regions of the country. In addition, since the inception of the system, the threat level has not been increased for any period that exceeded 6 weeks. An event that would cause NRC-regulated sites to maintain increased protective measures for a period of more than 60 days would likely mean a significant domestic attack had occurred. In this event, § 26.207(c) [Common defense and security] provides a means for extending the proposed 60-day exception period, as discussed with respect to that provision.

Proposed § 26.199(f)(2)(iv) would have clarified the instances in which security personnel would be subject to a collective work hour limit for certain instances in which multiple plant conditions exist. The NRC has not retained this provision for the final rule because § 26.205(d)(ii), in conjunction with the definition of *increased threat condition* as described in § 26.5 [Definitions], adequately addresses the applicability of the work hour requirements for circumstances in which multiple plant conditions (e.g., a unit outage and increased threat

condition) occur simultaneously. Specifically, § 26.205(d)(ii) states that during the first 60 days of an unplanned security system outage or increased threat condition, licensees need not meet the requirements of either § 26.205(d)(3) or (d)(5)(i). As a consequence, should an unplanned security system outage or increased threat condition occur at any time during a unit outage, security personnel subject to the work hour requirements would not be required to meet the minimum day off requirements of § 26.205(d)(3) or (d)(5)(i) during the first 60 days of the unplanned security system outage or increased threat condition.

Proposed § 26.199(f)(2)(iv) would have also clarified the applicability of the collective work hour controls to instances in which a threat level increases and then decreases. In the final rule, the NRC has defined an *increased threat condition* in § 26.5 as "an increase in protective measure level, relative to the lowest level applicable to the site during the previous 60 days, as promulgated by an NRC advisory." Accordingly, any time a threat level changes, whether by increasing or decreasing, the determination of whether a site is in an increased threat condition, for purposes of applying the work hour requirements of Subpart I, is made by comparing the current threat level with the lowest level applicable to the site during the previous 60 days.

Proposed § 26.199(f)(2)(v) would have clarified the applicability of the collective work hour limits for security personnel during multiple consecutive and concurrent plant conditions. The NRC has not retained this provision for the final rule because the requirements in § 26.205(d)(5) and (d)(7), in conjunction with the definition of *increased threat condition* as described in § 26.5, adequately define the requirements applicable to multiple consecutive and concurrent plant conditions. In the case of multiple consecutive increases in threat conditions, § 26.205(d)(ii) would permit a 60-day exception from the minimum day off requirements, with the 60 days beginning with each increase. As described in the preceding paragraph, should the threat level decrease, the determination of which work hour requirements are applicable (i.e.,

whether the increased threat level exception applies) depends upon a comparison of the current threat level to the lowest level applicable in the previous 60 days.

Proposed § 26.199(f)(2)(vi) would have established 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 have established 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. The NRC has not retained this provision for the final rule because the requirement in § 26.205(d)(5) in conjunction with the definition of *increased threat condition* as described in § 26.5, adequately define the requirements. 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 to the level of week 1, the beginning of the maximum 60-day exception period would be the beginning of week 1 because the definition of increased threat condition is based upon an increase from the lowest level of protective measures in the past 60 days. The requirements 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. As a consequence, § 26.205(d)(5), in conjunction with the definition of *increased threat condition* in § 26.5, establishes requirements applicable to changes in threat conditions that are consistent with the work hour controls order EA-03-038 requires.

Section 26.205(d)(6) permits licensees to extend the 60-day exception periods in § 26.205(d)(4) and (d)(5) for each individual in 7-day increments for each non-overlapping 7-day period in which the individual has worked not more than 48 hours during the unit or security system outage or increased threat condition. For example, during weeks 5 and 6 of a 10-week outage, an individual may work 42-hour work weeks because of reduced demand for his or her

skills during those weeks of the outage. That individual would then be eligible to work an additional 2 weeks beyond the 60-day exception period under the minimum day off requirements applicable to the first 60 days of an outage. The NRC added this provision to the final rule partly in response to public comment on the proposed rule that the exception for outage periods should be extended to 10 weeks. As described with respect to § 26.205(d)(4), the NRC does not believe it is appropriate to extend the outage exception period to 10 weeks without restriction because of the increased potential for cumulative fatigue when individuals work at the limits established by § 26.205(d)(4) for extended periods of time. However, during public meetings on the proposed rule, stakeholders also commented that during extended outages individuals do not always work an outage schedule for the entire outage but may have periods of reduced activity that provide opportunity for individuals to recover from cumulative fatigue. The break requirements exception allowed by § 26.205(d)(6) acknowledges this circumstance. The provision accommodates longer outages without increasing the risk of worker fatigue by allowing licensees to extend the outage exception, and therefore the reduced requirements applicable to outages, by taking credit for these periods of reduced work hours. As a result, this requirement also provides licensees the flexibility of planning outages longer than the normal 60-day exception period by incorporating periods of reduced work hours appropriate to maintaining worker FFD over an extended duration outage. In addition, this provision also applies to increased threat conditions and provides a mechanism for a limited extension of the reduced requirements applicable to scheduling individuals performing security functions during increased threat conditions.

Proposed § 26.199(f)(3) would have permitted 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 § 26.199(f)(3)(i) through (f)(3)(iii) of the proposed rule were met. The criteria in proposed § 26.199(f)(3)(i) through (f)(3)(iii) would have

permitted licensees to control work hours to a higher collective work hour limit under certain occasional, short-term exigent circumstances. The NRC has not retained this provision for the final rule because the requirements in § 26.205(d)(3) and (d)(6), and § 26.207 [Waivers and exceptions] adequately define the requirements applicable to these circumstances.

The objective of proposed § 26.199(f)(3) would have been to establish a regulatory framework that accommodated 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 requirements of the final rule provide licensees the flexibility to accommodate these circumstances in a manner that is consistent with reasonable assurance of worker FFD. Section 26.205(d)(3) establishes minimum day off requirements that accommodate variation in workload because it does not require a minimum number of days off each week but requires licensees to ensure that individuals have an average number of days off over the duration of a shift cycle of up to 6 weeks. As a consequence, individuals are able to work up to 72 hours in a week, to the extent that they are still able to meet the minimum days off requirement for the shift cycle. For example, individuals on 12-hour shifts can work 72 hours per week for 2 weeks, and still have enough days off to work an average of 45 hours per week for the remaining 4 weeks of a 6-week cycle. Section 26.205(d)(3) also accommodates circumstances that may require increased work hours for more extended periods of time. Again, as an example, § 26.205(d)(3)(iii) requires an average of 2.5 days off per week for individuals performing the job duties specified in § 26.4(a)(1) through (a)(4). Individuals can meet this requirement while working an average of 54 hours per week. This limit is comparable to the limit that would have been required by § 26.199(f)(3)(ii) of the proposed rule, which would have restricted the exception allowed by § 26.199(f)(3) to a group collective work hour average of not more than 54

hours per person per week. Section 26.205(d)(6) can also accommodate limited unplanned extensions of an outage beyond the 60-day exception period, provided individuals have periods of reduced work hours that qualify for the 7-day extensions. Such circumstances may arise if unexpected complications in an outage task occur that cause the work to be deferred until later in the outage, leaving the assigned work crew with a reduced period of activity.

The NRC also notes that the work hour limits of Subpart I are only applicable to a limited scope of personnel and therefore not all exigent circumstances would necessarily involve individuals or duties subject to these controls. In addition, should the circumstances require increased work hours by individuals who perform the duties specified in § 26.5(a)(1) through (a)(5), the provisions of § 26.207 [Waivers and exceptions] address waivers of the work hour requirements when necessary to prevent or mitigate conditions adverse to safety and provide exceptions from the requirements when necessary to ensure common defense and security and allow adequate staffing during declared plant emergencies.

Proposed § 26.199(f)(4) would have prohibited licensees from repeatedly permitting the collective work hours of any job duty group to exceed an average of 48 hours per person per week. The final rule does not retain this requirement because the NRC has deleted collective work hour control requirements from the final rule. As a consequence, a limit on repeatedly exceeding the collective work hour limit is not necessary for the final rule.

Proposed § 26.199(f)(5) would have permitted licensees to exceed any collective work hour limit of proposed § 26.199(f) if the licensee submitted and obtained advance approval of a written request to the NRC that included the information in proposed § 26.199(f)(5)(i) through (f)(5)(iii). The primary objective of this provision was to 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 § 26.199(f) of the proposed rule. As described with respect to § 26.205(d)(6),

§ 26.205(d)(6) provides a mechanism in the final rule for licensees to establish work hour schedules for extended outages without the need for NRC approval of a written request and therefore allows licensees to directly and more simply address the circumstances that would have otherwise been handled through the process that proposed § 26.199(f)(5) would have required.

Section 26.205(d)(7) establishes requirements for the control of work hours during unit and planned security system outages that closely follow a preceding outage. This requirement retains, with limited modifications, the requirements in proposed § 26.199(g) [Successive plant outages].

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 § 26.205(d)(7) is to ensure that the potential for cumulative fatigue is adequately addressed through appropriate work schedule controls when limited opportunity exists for recovery between successive periods of intensive work schedules. The requirement applies to unit and planned security system outages that follow the preceding outage by less than 2 weeks. A minimum of 2 weeks under normal work hours (e.g., nominal 40-hour workweek) provides 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 provision requires licensees to, in effect, treat outages that follow a preceding outage by less than 2 weeks as a continuation of the first outage. Specifically, licensees are required to apply the requirements of § 26.205(d)(4) through (d)(6) based upon the number of days that have elapsed since the first outage in the series began. For example, if a refueling outage lasts 30 days, but the plant encounters difficulties during power ascension a day after exiting the refueling outage and enters a new outage, then the 60-day exclusion period must be calculated from the beginning of the refueling outage.

In developing § 26.205(d)(7), the NRC revised § 26.199(g) [Successive plant outages] of the proposed rule to include planned security system outages. The NRC considered planned security system outages to be similar to unit outages with respect to the potential for cumulative fatigue and the fact that they are under the control of the licensee. The NRC did not include unplanned security system outages and increased threat conditions in this provision because the NRC considered these conditions to be largely outside the control of the licensee and including this restriction on unplanned security system outages and increased threat conditions could limit licensee ability to provide necessary security staffing.

The NRC also revised § 26.199(g) of the proposed rule to apply to individuals who work successive outages, separated by less than 2 weeks, for a licensee. The proposed provision was limited to successive outages at a licensee's site. Public comment on the proposed rule noted that several companies own and operate reactors at multiple sites and it is not uncommon for these companies to develop specialty work groups and deploy these work groups to all of their sites. Section 26.205(d)(7) addresses this comment and is applicable to individuals who work in outages in close succession for a licensee, regardless of whether the outages occurred at a single site or more than one site. The final rule is applicable to a larger proportion of the individuals that work successive unit outages and thereby provides greater assurance that these individuals are subject to work hour controls that are appropriate for sustained and successive periods of extended work hours associated with outage work schedules. The NRC notes that, like the proposed provision, § 26.205(d)(7) of the final rule is not applicable to individuals who may work outages in close succession if those outages are for different licensees. The NRC acknowledges that the potential for cumulative fatigue is likely to be no different for these individuals than for individuals working successive outages for the same licensee. However, as described with respect to § 26.205(d)(4), the NRC considered the substantial burden of tracking work hours from one licensee to another and determined that the

expected benefit did not warrant the additional burden.

Section 26.205(e) [Reviews] has been 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 § 26.4(a). This section replaces with substantive changes the requirements in § 26.199(j) of the proposed rule. The NRC revised the review requirements to eliminate reviews related to the collective work hour limits that were deleted from the final rule and to add a review requirement for the implementation of the requirements in § 26.205(d)(3).

Work hour controls in proposed § 26.205(d) would provide licensees with substantial flexibility in controlling work hours. Accordingly, periodic self-assessments are needed for the licensee to maintain reasonable assurance that they are implementing the specific work hour control provisions of § 26.205(d) consistent with the general performance objective in § 26.23(e). In addition, it is necessary for the self-assessments to be scheduled in a manner that ensures 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 is particularly important to include those periods of time in any assessment of the effectiveness of a licensee's work hour controls. Accordingly, licensees are required to conduct a minimum of two reviews per calendar year. The two reviews need not cover periods of equal duration but must collectively cover the entire calendar year. If any plant or security system outages or increased threat conditions occurred since the licensee completed the most recent review, the licensee shall include in the review an evaluation of the control of work hours during the outages or increased threat conditions. Licensees shall complete the review within 30 days of the end of the review period.

Section 26.205(e)(1) requires licensees to review the actual work hours and

performance of individuals who are subject to this section for consistency with the requirements of § 26.205(c), so that licensees can determine if they are scheduling individuals with the objective of preventing impairment from fatigue due to the duration, frequency, or sequencing of successive shifts. This review is consistent with the performance-based approach in § 26.205(c).

Section 26.205(e)(1)(i) requires the licensees to assess individuals whose actual hours worked during the review period exceeded an average of 54 hours per week in any shift cycle while the individuals' work hours are subject to the requirements of § 26.205(d)(3). Individuals that average more than 54 hours over a shift cycle have a substantial number of extended work days, or have received minimal days off, or both. Although the objective of the minimum day off requirements of § 26.205(d)(3) is a maximum average work week of 48 hours, the requirements do not prevent individuals from exceeding an average of 54 hours per week. The requirement is necessary to ensure that licensees fully evaluate the work hours and performance of these individuals. 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 final rule requires 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.

Section 26.205(e)(1)(ii) requires that licensee assessments include individuals who were granted more than one waiver during the review period. This provision requires licensees to assess the work hours and performance of these individuals to ensure that licensees adequately evaluate whether an individual's abilities to safely and competently perform their duties had actually been compromised while working under a waiver. This requirement is necessary to ensure that licensees' use of waivers did not result in degraded worker fitness-for-

duty.

Section 26.205(e)(1)(iii) requires that the licensee assessments include individuals who were assessed for fatigue in accordance with § 26.211 [Fatigue assessments] during the review period. This section requires 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 requirement is necessary to ensure that licensee fatigue assessments are consistent with worker performance and are providing an effective basis for licensee fatigue management decisions.

Section 26.205(e)(2) requires licensees to review each individual's 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 § 26.205. The minimum day off requirements of § 26.205(d)(3) through (d)(5) provide assurance that licensees are managing cumulative fatigue at a gross level, and an indication of whether staffing is adequate to support the objectives of the rule. However, there is a potential that individuals with specialized skills may work a disproportionate number of hours and, consequently, may be more susceptible to fatigue than others. Accordingly, § 26.205(e)(2) requires licensees to review work hours and waivers of the work hour controls to provide assurance that fatigue is properly managed for all jobs.

Section 26.205(e)(3) requires licensees to document the methods used to conduct their reviews and the results of the reviews. The NRC will use the documentation during site inspections as a means of assuring compliance with the regulations. The methods and results of the reviews are indicative of a licensee's performance in managing the fatigue of its workers who are subject to the requirements of this 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.

Section 26.205(e)(4) requires 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 are required to maintain the documentation that is necessary for NRC reviews of licensees' compliance with the work hour controls within the licensees' existing corrective action programs. The requirement is 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 will 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 are 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 requirements and maintaining effective fatigue management programs.

Section 26.207 Waivers and exceptions.

Section 26.207 permits licensees to authorize waivers from the work hour requirements in § 26.205(d)(1) through (d)(5)(i) for conditions that meet the two criteria specified in this section. Section 26.207 contains the revised requirements in proposed § 26.199(d)(3) and 26.199(h) and (i) of the proposed rule. The final rule consolidates these requirements into a

single section to improve the organization of Subpart I. Although the provisions are renumbered, the NRC made only limited changes to the requirements for the final rule.

Section 26.207(a) permits licensees to grant a waiver of the work hour controls in § 26.205(d)(1) through (d)(5)(i). Exceeding the individual work hour limits is justified for limited circumstances in which compliance with the work hour requirements could have immediate adverse consequences for the protection of public health and safety or the common defense and security. Limited use of waivers is also consistent with the Commission's position stated in the NRC's Policy on Worker Fatigue. However, as specified in § 26.207(a)(2), which contains the requirements in proposed § 26.199(d)(3)(ii), the NRC expects a licensee to grant waivers only to address circumstances that it cannot reasonably control.

Section 26.207(a)(1)(i) requires an operations shift manager to determine that the waiver is necessary to mitigate or prevent a condition adverse to safety, or a security shift manager to determine that the waiver is necessary to maintain site security, or a site senior-level manager with requisite signature authority to make either determination. This section establishes one of two criteria in the final rule for granting a waiver from the individual work hours requirements. This section replaces proposed § 26.199(d)(3)(i)(A), with limited editorial revisions.

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 and that some licensees abused the authority to grant deviations from the work hour guidelines. Section 26.207(a)(1)(i) more clearly articulates the NRC's expectations with respect to exceeding the work hour limits; licensees must limit the granting of waivers from the work hour limits to circumstances in which such a waiver is necessary to prevent or mitigate a condition adverse to safety or to maintain the security of the

plant. The criterion in the final rule limits waivers to conditions that are infrequent while still permitting waivers that are necessary for safety or security. For example, § 26.207(a)(1)(i) permits a licensee to grant a waiver from a work hour requirement if necessary to prevent a condition adverse to safety, if compliance with the work hour requirement will cause the licensee to violate other NRC requirements, such as the minimum onsite staffing requirements in 10 CFR 50.54(m), or if a delay in the recovery of failed plant equipment that is necessary for maintaining plant safety will occur. Similarly, the NRC considers it appropriate to grant a waiver from the work hour requirements if necessary to prevent a condition adverse to safety or if compliance with the work hour requirements 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 § 26.207(a)(1)(i) was the subject of considerable stakeholder comment and discussion during the public meetings described in the preamble to the proposed rule. 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, the potential for worker fatigue in conditions that 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 limits on the basis that granting the waiver will not have an adverse impact on safety or security. The preamble to the proposed rule details the NRC's decision not to incorporate industry's comment on this provision.

Section 26.207(a)(1)(i) further requires 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 final rule requires 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 is 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 the preamble to the proposed rule, 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 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 individuals making these determinations are not unduly influenced by schedule pressures. The NRC noted that some licensees had delegated the authority to authorize deviations to organizational levels that appeared to be inconsistent with the guidelines in the NRC's Policy on Worker Fatigue, which recommend that the plant manager or plant manager designee authorize deviations from the guidelines. Accordingly, § 26.207(a)(1)(i) permits senior site managers with the signature authority of operations shift supervisors to make the safety determinations that are required to grant waivers and senior site managers with the signature authority of security shift supervisors to make the security determinations required to grant waivers.

Section 26.207(a)(1)(ii) establishes the second of two criteria for granting a waiver from the individual work hour controls of § 26.205(d)(1) through (d)(5)(i). This section contains, with revision, the requirements in § 26.199(d)(3)(i)(B) of the proposed rule. Section 26.207(a)(1)(ii)

requires 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 §§ 26.29 [Training] and 26.203(c) [Training and examinations], must assess the individual face to face and be reasonably sure that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver is sought. These determinations 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 §§ 26.29 [Training] and 26.203(c) [Training and examinations] provides the KAs that are essential for a supervisor to make valid assessments in this regard. Among other FFD topics, the training addresses 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 training is necessary for individuals to perform these assessments.

The NRC revised the proposed rule to account for the situation in which no supervisor qualified to direct the work is on site. To address this circumstance, § 26.207(a)(1)(ii) of the final rule states that a supervisor who is qualified to provide oversight of the work to be performed by the individual can make the assessment if he or she is trained in accordance with the requirements of §§ 26.29 [Training] and 26.203(c) [Training and examinations]. Although this individual may be less familiar with the details of how the work is to be performed, the exception prevents the substantial burden of a licensee requiring a supervisor who is qualified to direct the work to report to the site to perform the assessment, as well as preventing the potential fatigue of the supervisor if called in during the night.

Section 26.207(a)(1)(ii) further requires that supervisors must perform the assessment

face to face with the individual to which the waiver will apply. This requirement ensures that the supervisor who is performing the assessment has the opportunity to observe the individual's appearance and behavior and note any indications of fatigue (e.g., decreased facial tone, rubbing of eyes, slowed speech). The supervisor can also interact with the individual to assess his or her ability to continue to safely and competently perform his or her duties during the period for which the waiver will be granted.

Section 26.207(a)(1)(ii) also requires 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 that 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 whether (1) the individual had adequate opportunity to obtain sufficient rest, considering the length and sequencing of break periods, (2) the available sleep periods occurred during the night or at other times when sleep quality may be degraded, and (3) the potential exists 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.
Section 26.207(a)(1)(ii) in effect requires 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 assessment, the NRC also considered the need for licensees to be able to focus the assessment on information that is readily available and could be verified.

Section 26.207(a)(1)(ii) further requires that the supervisory assessment for granting a waiver address the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions and whether it is necessary to establish controls and conditions under which the individual is permitted to perform work. This 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, § 26.207(a)(1)(ii) requires 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.

Section 26.207(a)(1)(ii) also requires 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 are not 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 requirement to consider establishing controls and conditions is 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.

Section 26.207(a)(2) requires licensees, to the extent practical, to grant waivers only in circumstances that could not have been reasonably controlled. This section contains the requirement presented in § 26.199(d)(3)(ii) of the proposed rule. This requirement is necessary

because conditions for meeting the waiver criteria that are specified in § 26.207(a)(1) could routinely result from inadequate staffing or work planning. Licensees have authorized deviations from their technical specification limits on work hours for such 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, § 26.207(a)(2) prohibits 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 are not limited to, equipment failures or a sudden increase in the personnel attrition rate.

Section 26.207(a)(3) requires that the face-to-face supervisory assessment required by § 26.207(a)(1)(ii) 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 will provide a valid indication of the potential for worker fatigue during the extended work period. This section contains the requirements presented in § 26.199(d)(3)(iii) of the proposed rule. This requirement is needed 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 final rule requires 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.

Section 26.207(a)(3) also establishes 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 will 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 this 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.

Section 26.207(a)(4) requires licensees to document the bases for granting waivers from the individual work hour controls of § 26.205(d). This section contains the requirement presented in § 26.199(d)(3)(iv) of the proposed rule. This section requires 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 required by § 26.207(a)(1). This documentation is 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 § 26.205(e) [Reviews].

Section 26.207(b) [Force-on-force tactical exercises] of the final rule relieves licensees from the requirements of § 26.205(d)(3) by allowing them to exclude shifts worked by security personnel during the actual conduct of NRC-evaluated force-on-force tactical exercises when calculating the individual's number of days off. This provision is an addition to the requirements of the proposed rule and is similar to a slightly different exception contained in Order EA-03-08 that applied to group work hour controls. The NRC believes this provision is appropriate in order to provide licensees flexibility in accommodating the NRC-evaluated tactical exercises, which are not under a licensee's full control. For example, it allows licensees to use security personnel on their normally scheduled days off to support the conduct of the exercise without violating the rule. The exception in Order EA-03-08 also applied to other force-on-force tactical exercises (i.e., any not evaluated by the NRC), but the NRC believes this is not an appropriate exception for the minimum days off requirement because these exercises can be fully planned and scheduled by licensees in advance in a manner that complies with the requirements. Nevertheless, the more limited exception should provide adequate flexibility to licensees given that (1) the final rule removes all restrictions on group work hour controls for security personnel, and (2) the exception applies to all security personnel working during affected shifts (including staff that do not participate in the exercise) even though the minimum days off requirement applies to security personnel on an individual basis. In contrast, the group work hour controls applied to security personnel collectively. During the limited exception period for these triennial (every 3 years) NRC-evaluated exercises, the requirements in § 26.205(d)(1) and (d)(2) provide reasonable assurance that fatigue does not impair the ability of these individuals to safely and competently perform their duties.

Section 26.207(c) [Common defense and security] provides a licensee relief from the work hour control requirements of § 26.205(d) upon written notification from the NRC, for the purpose of assuring the common defense and security for a period the NRC

defines. This section contains the requirements presented in § 26.199(h) of the proposed rule. The exception granted by this section provides necessary relief from the requirements of the work hour controls 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. This section also indicates that the NRC would provide such relief in writing.

Section 26.207(d) [Plant emergencies] adds the potential to temporarily waive the requirements of § 26.205(c) and (d) during declared emergencies, as defined in the licensee's emergency plan. This section contains the requirements presented in § 26.199(i) of the proposed rule. 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 § 26.205(c) and (d). The objective of the temporary exemption is 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 rule would require licensees to again comply with the work hour controls.

Section 26.209 Self-Declarations.

Section 26.209(a) retains, with limited editorial changes, the requirements presented in § 26.199(e) of the proposed rule. Section 26.209(a) requires licensees to take immediate action in response to a self-declaration (as discussed with respect to § 26.203(b)(1)) by an individual who is working under, or being considered for, a waiver from the work hour controls in § 26.205(d)(1) through (d)(5)(i). Licensees are required to immediately stop the individual from

performing any duties listed in § 26.4(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, this section requires the licensee to immediately take action to relieve the individual. For example, the licensee should 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 final rule retains this requirement of the proposed rule because correct performance of the duties specified in § 26.4(a) is critical to 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 § 26.205(d)(1) through (d)(5)(i). Individuals working extended hours under a waiver will 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 will effectively provide an assessment of his or her ability to continue to safely and competently perform these critical duties. Several studies indicate 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 makes a self-declaration of fatigue is potentially more impaired than he or she realizes.

Section 26.209(a) does not require that licensees immediately 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. The failure to meet minimum staffing or similar requirements will, 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 can implement any fatigue mitigation strategies they deem necessary while the individual remains on duty. Fatigue mitigation measures in these circumstances include, but are not 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).

Section 26.209(b) establishes the requirements for returning an individual to duty following a self-declaration under the conditions described in § 26.209(a). These provisions allow the individual to be reassigned to duties that are not subject to work hour requirements, if the individual is fit for such duties, and requires that the individual have a break of at least 10 hours before returning to duties that are subject to the work hour requirements of Subpart I.

Section 26.209(b)(1) permits licensees to reassign an individual who has made a self-declaration of fatigue to perform other duties than those specified in § 26.4(a). This section contains with limited editorial revisions the requirements presented in § 26.199(e)(1) of the proposed rule. The final rule includes this flexibility because, although an individual may not be fit to perform the activities specified in § 26.4(a), he or she may be able to safely and competently perform other duties. Other duties can include, but are not 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 final rule permits licensees to reassign individuals who make a self-declaration of fatigue to other duties, if the results of a fatigue assessment (as required under § 26.211 [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 will not have the potential to adversely impact public health and safety or the common defense and

security.

Section 26.209(b)(2) requires licensees 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 § 26.4(a). This section contains, with limited editorial revisions, the requirements presented in § 26.199(e)(2) of the proposed rule. The final rule includes this requirement to ensure that individuals who have self-declared are 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 § 26.205(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 final rule precludes 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 NRC RIS 2002-07 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.

Section 26.211 Fatigue assessments.

Section 26.211 requires licensees to conduct fatigue assessments under several conditions and contains, with limited editorial changes, the requirements presented in proposed § 26.201. The numbering and content of the paragraphs in § 26.211 remain consistent with that of proposed § 26.201. These conditions, specified in § 26.211(a)(1) through (a)(4), include for cause, after a self-declaration, after an event that requires post-event drug and alcohol testing, and as a followup to returning an individual to work after a self-declaration. The assessments are 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 in which a plant event requires drug or alcohol testing as specified in § 26.31(c) [Conditions for testing], this section requires the licensee to conduct a fatigue assessment to determine whether fatigue contributed to the event.

Work hour requirements are necessary, but not sufficient, to manage worker fatigue effectively. 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, individuals differ substantially in their 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 hour requirements of § 26.205 provide only partial assurance that individuals are not fatigued. Therefore, fatigue assessments are 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. A large body of research 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 § 26.211(a)(1) through (a)(4) is for licensees to address instances of worker fatigue appropriately, including those that are not prevented by the work hour requirements, regardless of the number of hours that the subject individual has worked or rested. As discussed with respect to § 26.211(c), these assessments 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.

Section 26.211(a)(1) specifies that licensees must perform a fatigue assessment, in addition to any other testing that required under §§ 26.31(c) [Conditions for testing] 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 requirement is 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 will help to determine if fatigue was the cause for the perceived impairment when 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. 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 decisionmaking, 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).

Section 26.211(a)(1) does 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 protected area (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, § 26.211(a)(1) excludes napping during a break period as a condition for which the final provision requires a for-cause fatigue assessment.

Section 26.211(a)(1) also permits 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 requirement related to for-cause fatigue assessments, the NRC considered stakeholder comments during the public meetings described in the preamble to the proposed rule. 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 requirement permits licensees to assess only fatigue if there are no indications of possible substance abuse.

Section 26.211(a)(1) also permits licensees to conduct drug and alcohol testing, without a fatigue assessment, when the licensee has reason to believe that the observed condition is not caused by fatigue. The NRC considered stakeholder comments at the public meetings described in the preamble to the proposed rule 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 is 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, a fatigue assessment will have no benefit.

Section 26.211(a)(2) requires licensees to conduct a fatigue assessment if an individual makes a self-declaration that he or she is not 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 requirements in § 26.205, are appropriately addressed, regardless of the number of hours the individual has worked or rested. Former § 26.27(b)(1) required 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 is not 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, is 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 final rule does 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 is consistent with § 26.205(d)(2)(i), which establishes required break times between work periods, and is generally considered sufficient to address most acute fatigue conditions.

As discussed with respect to § 26.211(c), a fatigue assessment provides 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 § 26.203(b)(1)(ii), licensees are 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 final requirement for fatigue assessments of individuals who have self-declared, the NRC considered research on subjective assessments of alertness. Self-declarations are generally 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 will 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.

Section 26.211(a)(2) also specifies 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 final rule 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 final 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 requirement specifies 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 § 26.211(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 is required for cause in accordance with § 26.211(a)(1).

Section 26.211(a)(3) specifies that licensees must perform a fatigue assessment after

an event that requires drug or alcohol testing, as required in § 26.31(c)(3).

Section 26.31(c)(3)(i) through (c)(3)(iii) specifies the events and conditions requiring post-event drug and alcohol testing. A fatigue assessment is also 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 will also provide the basis for subsequent management actions for fatigue management, as required by § 26.211(c) (e.g., relieving an individual of duties or requiring additional fatigue mitigation actions). Further, the fatigue assessment will provide insights concerning the effectiveness of the licensee's fatigue management program.

Consistent with § 26.31(d)(5)(ii), the requirement specifies 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 is irrelevant to the immediate protection of public health and safety or the common defense and security.

Section 26.211(a)(4) requires licensees to perform a followup fatigue assessment if an individual is 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 provision is 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 ensures that the individual is capable of performing his or her duties safely and competently during the upcoming work period. It also provides 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).

Section 26.211(b) requires that either a supervisor or a staff member of the FFD program, who is trained in accordance with the requirements of §§ 26.29 [Training] and 26.203(c) [Training and examinations], must conduct any fatigue assessment that is required under § 26.211. Under § 26.211(c), fatigue assessments 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 26.203(c) provides the KAs that are essential to a supervisor's or FFD program staff member's ability to make valid assessments in this regard. Among other FFD program topics, the training addresses (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. Section 26.29(b) [Policy] also requires individuals to demonstrate successful completion of the training by passing a comprehensive examination that addresses the KAs.

Section 26.211(b) further requires that supervisors or FFD program staff members must perform the fatigue assessment face to face with the subject individual. This requirement

ensures 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.

Section 26.211(b)(1) prohibits individuals who observe another individual exhibiting indications of impaired alertness from performing the for-cause fatigue assessment of that individual. Without this 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 § 26.211(c), fatigue assessments 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 are conducted for cause, an independent third party shall perform the fatigue assessment to provide reasonable assurance of an objective assessment.

Section 26.211(b)(2) prohibits individuals from performing a post-event fatigue assessment in those circumstances specified in § 26.211(b)(2)(i) through (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. This requirement provides 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.

Section 26.211(b)(2)(i) prohibits 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 final rule prohibits these individuals from performing fatigue assessments under the specified conditions.

Section 26.211(b)(2)(ii) prohibits individuals from performing a post-event fatigue assessment if they performed a fatigue assessment of the individuals who were performing or directing the work activities during which the event occurred within 24 hours before the event occurred. These individuals may have a conflict of interest. For example, if an individual previously self-declared fatigue, but a fatigue assessment determined he or she was fit to continue work and an event subsequently occurred that required the subject individual to be assessed again, then the supervisor who performed the first assessment may avoid adverse action for the previous determination by performing the post-event fatigue assessment and erroneously determining that the individual was not fatigued. The final rule prohibits these individuals from performing fatigue assessments under the specified conditions.

Section § 26.211(b)(2)(iii) prohibits individuals from performing a post-event fatigue assessment if they evaluated or approved a waiver of the limits specified in § 26.205(d)(1) through (d)(5)(i) 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. This provision limits the potential for bias in assessments that can result from prior involvement in assessing the individual or responsibility for the work activities associated with the event.

Section 26.211(c) requires that fatigue assessments must provide the information necessary for management decisions and actions in response to the circumstance that initiated the assessment. This information is 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. Section 26.211(c) provides 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 § 26.211(c)(1)(i) through (c)(1)(iii) specify the minimum considerations for fatigue assessments.

In determining the scope of the assessments, the NRC considered the need for licensees to be able to focus the assessment on information that is readily available and verifiable. Section 26.211(c) requires the assessment to address the three work schedule factors described in § 26.211(c)(1) through (c)(3), which 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.

Section 26.211(c)(1)(i) specifies the first criterion that fatigue assessments will address, 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 will 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).

Section 26.211(c)(1)(ii) specifies the second criterion that fatigue assessments will address, 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 will 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, and (4) other individual factors or information provided by the individual (such as any personal issues that may 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 has 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 7 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.”

Section 26.211(c)(1)(iii) specifies the third criterion that fatigue assessments will address, circadian variations in alertness and performance. Section IV.D discusses the impact of such variations on an individual’s ability to safely and competently perform his or her duties. Licensees can assess the potential for circadian degradations in alertness and performance by considering the time of day or night during which the work was or will be performed and whether the time period coincides with a circadian variation through in the individual’s level of alertness.

Section 26.211(c)(2) requires that individuals must provide complete and accurate information that may be required by the licensee to address the factors listed in § 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, many other factors can affect worker fatigue, not all of which may be readily apparent to a licensee. As a consequence, individuals and licensees share the responsibility for effective assessment and management of fatigue which 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, as well as 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, individuals differ substantially in their 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 substantively improves 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 is or will be performed and whether the time period coincides 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.

Section 26.211(c)(2) also limits licensees' inquiries to only obtaining information from the subject individual that is necessary to assess the factors listed in § 26.211(c)(1). The fatigue assessment will 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 § 26.37 [Protection of information], licensees are required to keep any information from the individual's self-disclosures confidential.

Section 26.211(d) prohibits 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 § 26.205(d)(1) or that the individual has had the minimum rest breaks required in § 26.205(d)(2) or the minimum days off required in 26.205(d)(3) through (d)(5). The work hour controls of § 26.205(d)(1) and (d)(2) provide reasonable measures to prevent fatigue resulting from excessive work hours. However, these controls address only work hours and work schedules, 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 work hours requirements of § 26.205(d)(1) through (d)(5), it is neither practical nor possible to establish limits that will prevent fatigue for all individuals. Therefore, the final rule requires 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.

Section 26.211(e) requires that, following a fatigue assessment, the licensee must decide whether the individual may perform duties without a rest break, and, if so, whether controls and conditions must be established under which the individual may perform those duties. Examples of controls and conditions include, but are not limited to (1) a rest break, (2) peer review and approval of assigned job tasks, (3) assignment of job tasks that are non-repetitive in nature, (4) assignment of job tasks that are simple in nature, and (5) assignment to duties that are not important to the protection of public health and safety or common defense and security. Section 26.211(e) also requires licensees to ensure that any controls and

conditions that they determine to be necessary to return an individual to duty will be implemented.

Section 26.211(f) requires that licensees document the results of any fatigue assessments that were performed, the circumstances that necessitated the fatigue assessments, and any controls and conditions that were implemented. The documentation is necessary for NRC inspectors to evaluate the fatigue assessment component of licensees' FFD programs and for the licensee to conduct the reviews required under § 26.205(e) [Reviews]. The information that the final rule requires licensees to document will indicate how well a licensee's fatigue mitigation program at a site is performing.

Subpart J – [Reserved]

As a result of reorganization of the proposed rule, the provisions contained in Subpart J of the proposed rule have been moved to Subpart N of the final rule. This section is currently reserved.

Subpart K – FFD Programs for Construction

Section 26.401 General.

Section 26.401(a) provides that a licensee or other entity specified in § 26.3(c) may, at its discretion, establish, implement, and maintain an FFD program that meets the requirements of Subpart K for those individuals who are specified in § 26.4(f). Alternatively, if an FFD program for those individuals that meets the requirements of Subpart K is not established, those individuals must be subject to an FFD program that meets the requirements of Subparts A through H, N, and O of Part 26. The NRC recognizes that some new plants will be constructed near existing nuclear power plants, and it may be more efficient for the licensees of those plants to extend their existing FFD programs to cover the individuals specified in

§ 26.4(f). Therefore, this section of the final rule provides licensees and other entities flexibility to implement either the Subpart K program or a program meeting all of the requirements of Subparts A through H, N, and O. Subparts A through H, N, and O include all elements of the FFD program that apply to operating nuclear power plant licensees, except fatigue management requirements. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs. It also meets Goal 6 to improve clarity in the organization and language of the rule.

This section of the final rule differs in several respects from those sections of the former rule and the proposed rule that established the general applicability requirements for FFD programs during construction. The former rule did not specify the construction activities that would be subject to the FFD program. Consequently, it applied to all workers performing any construction activities, whether or not the structures, systems, and components (SSCs) under construction could have an impact on public health and safety or the common defense and security. In addition, it did not provide a choice between applying the FFD program in § 26.2(c) of the former rule or a complete Part 26 program to the new reactor construction workforce. The proposed rule also did not specify the individuals to whom the program would apply, thus making it applicable to the entire new reactor construction workforce. The proposed rule also did not provide the option that is included in § 26.401(a) of the final rule. The final rule provides greater flexibility to licensees and other entities than either the former rule or the proposed rule by giving them an option concerning the type of FFD program to apply. It also clarifies and narrows the scope of the group to which Subpart K applies. This is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The former rule in § 26.2(c) imposed FFD requirements on construction permit holders "with a plant under active construction" but did not define that term. The proposed rule in § 26.3(e) would have required an FFD program for construction following NRC authorization to

construct. However, the NRC recognizes that there may be a period of time that elapses between the authorization to construct and the commencement of specific construction activities that have the potential to affect public health and safety and the common defense and security when the nuclear power plant begins operations. Therefore, the final rule clarifies that an FFD program for construction is not required until a licensee or other entity begins "fabricating, erecting, integrating, and testing the nuclear power plant SSCs that are required by the Commission's rules and regulations to be described in the site safety analysis report, preliminary or final safety analysis report, or physical security or safeguards contingency plans, and the installation of their foundations, including the placement of concrete."

In addition, the FFD program for construction in the final rule applies only to construction activities that are performed at the location where the new plant will be constructed and operated. The NRC added this phrase to the definition of construction activities in § 26.5 of the final rule to clarify that any fabrication, integration, or testing of safety- or security-related SSCs that is not performed within or near the licensee's or other entity's owner-controlled area in which the new plant will be operated would not be subject to Subpart K. For example, fabricating, integrating, and testing safety- or security-related SSCs at a vendor's or manufacturer's facility that is located in another city, state, or country would not be subject to Subpart K, whereas producing (i.e., “fabricating”) the concrete to be used for the foundation of the reactor building in a facility located on the construction site would be subject to Subpart K (although the construction of the cement mixing facility would not). The NRC anticipates that the focus of the Subpart K program on construction activities performed at the location where the new plant will be constructed and operated will lead licensees and other entities to ensure that the program covers all those individuals who perform construction activities within the footprint of the new power reactor (e.g., the exterior boundary of the reactor building once it is completed) as well as the nearby areas where safety- and security-related SSCs will be

installed and operate when the plant begins operations.

The NRC considered whether the FFD program for construction should also cover individuals who construct safety- and security-related SSCs at a vendor's or manufacturer's facility that is geographically remote from the location where the new plant will be operated. Because of the modular design of new reactors, many of the safety-related SSCs that will be relied on to protect public health and safety will be fabricated by vendor personnel at remote locations and transported to the site for installation and integration. Similarly, the small, complete nuclear reactors that may be constructed by manufacturing licensees under Part 52 will also be constructed at remote locations and transported to the site for installation and integration. However, because of the complexity of the technical and regulatory issues raised by imposing FFD requirements on these entities, the staff has decided to defer adopting requirements for reactor manufacturing facilities, which were included in the proposed rule, and has declined to impose a Subpart K program on modular fabrication facilities located at a distance from a nuclear power plant construction site at this time.

The former rule and the proposed rule also did not limit the applicability of the FFD program to individuals who are constructing only safety- or security-related SSCs. However, the NRC recognizes that there will be other construction work being performed at the location where a new plant will be constructed and operated that will not have the potential to affect public health and safety or the common defense and security when the nuclear power plant begins operations, such as constructing a building that will be used only for training or administration purposes. The NRC does not intend that individuals who are performing these other construction activities must be subject to the FFD program. Therefore, the final rule also limits the scope of the requirements to cover only those individuals who are constructing (i.e., fabricating, integrating, testing, and installing foundations) these specific SSCs. Thus, as one example of a safety-related SSC, the rule requires individuals who are constructing the

containment structure that surrounds the reactor to be subject to an FFD program because the containment is relied on to mitigate the consequences of accidents that could result in potential offsite exposure. Similarly, individuals who are constructing safety-related SSCs, such as the central and secondary alarm stations, physical barriers, communications systems, guard towers, surveillance and detection systems, or installing locks and illumination systems, that will be necessary to implement the physical security and safeguards contingency plans that are required under 10 CFR Part 73 also are subject to an FFD program for construction.

Section 26.401(b) provides that licensees and other entities who intend to implement an FFD program under Subpart K shall submit an FFD program plan to the NRC for review and approval as part of the license or permit application. Licensees and other entities who intend to implement an FFD program for construction that meets all of the requirements of Subparts A through H, N, and O are not required to submit an FFD program plan. Submittal of an FFD program plan was not required by § 26.2(c) of the former rule or § 26.3(e) of the proposed rule, but is a logical and necessary component of Subpart K because of the flexibility that Subpart K provides in § 26.401(a) and (d). The FFD program plan will provide the information that the NRC needs to enable it to review and approve as a part of the license or permit application the particular FFD requirements that are selected for implementation by licensees and other entities. Subpart K provides licensees and other entities substantial flexibility in the design of the program to accommodate local circumstances and the logistical challenges associated with construction. The NRC believes this flexibility is necessary because it cannot reasonably anticipate all of the circumstances that may affect implementation of an FFD program for construction (e.g., proximity to a licensee testing facility, proximity to a population center that offers alternative collection sites, stability in the composition of the workforce at a specific site, variations in the need for an FFD program during different construction stages based on the potential risks imposed by the construction activities at each stage) and, therefore, could not

develop prescriptive requirements that would be appropriate for all potential circumstances. However, because Subpart K is not prescriptive and includes several new concepts (e.g., the fitness monitoring program, permission to use specimens other than urine for drug testing), NRC staff believes that it is necessary to verify that a licensee or other entity has understood the intent of the Subpart K provisions and will implement a program that meets that intent, including ensuring that any procedures used for testing specimens other than urine for drugs will be scientifically sound and legally defensible. The NRC believes that prior review and approval of the FFD program plan for construction will be more efficient than inspecting FFD programs for construction because it will significantly reduce the inspection resources necessary to ensure proper program implementation once construction has begun. In addition, delaying an evaluation of the program until an inspection can be scheduled, which may occur after construction has begun, could mean that an ineffective FFD program may be in place during early construction, when important tasks are being performed and errors resulting in faults could not be easily detected and corrected (e.g., the pouring of concrete). Finally, the emphasis on performance objectives in Subpart K, compared to the specific, prescriptive requirements in the remainder of the rule, means that the Subpart K requirements will be difficult to enforce without prior NRC approval of a licensee's FFD program plan.

The NRC expects the Subpart K program plans to consist of the FFD policy and procedures prepared by licensees or other entities, including, but not limited to, procedures for implementing either random testing or fitness monitoring and for performing drug and alcohol testing, and identification of the personnel covered by the FFD program. This requirement meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.401(c) provides that nothing prohibits the licensees and other entities listed in § 26.3(c) from subjecting the individuals described in § 26.4(f) to an FFD program that meets all of the requirements of Part 26, or program elements that meet all of the applicable

requirements of Part 26. This provision provides flexibility to licensees and other entities to cover all individuals with an FFD program that includes all the requirements of Part 26 or to adopt certain FFD requirements for individuals described in § 26.4(f) from Subpart K and certain FFD requirements from other subparts of Part 26, as long as the latter meet all of the applicable requirements of Part 26. In either case, workers conducting preliminary work that does not involve building any safety- or security-related SSCs of a facility are not required to be subject to an FFD program. This section allows licensees and other entities, if they so choose, to include fatigue management requirements under Subpart I in their FFD programs for reactor construction. It also allows licensees to mingle elements of the requirements of Subpart K and program elements under Subparts A through H, N, and O, as long as the elements selected from Subparts A through H, N, and O meet all of the requirements in Part 26 for that element. Because neither the former rule nor the proposed rule included this provision, the final rule provides greater flexibility than either the former rule or the proposed rule. This section achieves Goals 3 and 5 of the rulemaking to improve the effectiveness and efficiency of FFD programs and 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 26.403 Written policy and procedures.

Section 26.403 [Written policy and procedures] addresses the requirements related to the FFD policy for personnel listed in § 26.4(f) and the requirements related to the procedures for such FFD programs. These requirements are presented in separate sections to ensure that the requirements related to FFD policy and procedures are easy to locate within this section. This is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.403(a) requires FFD programs under Subpart K to ensure that a clear, concise, written FFD policy statement is provided to individuals who are subject to the program. Section 26.403(a) specifies that the policy statement must be written in sufficient detail to provide affected individuals with information on the program's expectations of them and the consequences that may result from a lack of adherence to the policy. Because Subpart K does not require licensees and other entities to provide site-specific FFD training to individuals, the FFD policy statement will be the primary means for communicating information with respect to, for example, the sanctions that are applied for confirmed positive, adulterated, substituted, or invalid test results, the types of specimens and 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, if the program includes random testing. Because of the likely large numbers and transient nature of construction workers involved in new reactor plant construction, requiring each of them to be provided with a copy of the FFD policy statement is the most effective and efficient means of ensuring that each individual listed under § 26.4(f) is informed of the contents of the policy. A clear and concise FFD policy statement that is provided to individuals subject to the program will promote their awareness of the site-specific FFD policy to which they are subject. This section satisfies Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, as well as Goal 7 to protect the privacy and other rights (including due process) of individuals who are subject to the rule.

If a licensee or other entity chooses, under § 26.401(d), to adopt FFD elements from Subparts A through H, N, and O of Part 26, the requirements established by those elements will need to be documented in the FFD policy and procedures, and in the FFD program plan. Also, notice will need to be provided to the relevant workers falling under the scope of the program, as required by this section of the rule.

The final rule differs in several other respects from the former rule and the proposed

rule. The former rule contained a simple cross-reference to the section of the former rule pertaining to the requirement to adopt an FFD policy and procedures in writing and did not describe or circumscribe the requirement. Thus, the policy and procedures requirement for FFD programs applicable to only the reactor construction workforce was the same as the requirement for other FFD programs. In contrast, the proposed rule did not contain any explicit cross-reference to the requirement pertaining to FFD program and procedures. However, the program and procedures section could be interpreted to apply to FFD programs applicable to the reactor construction workforce. The final rule both clarifies and adds flexibility to the requirement for an FFD policy statement and FFD procedures for FFD programs for construction by explaining the limited nature of the Subpart K FFD policy and procedures and indicating that they need to be provided only to those persons subject to the Subpart K FFD program. This is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.403(b) requires FFD programs under Subpart K to develop, implement, and maintain written procedures that address the topics specified in section (b)(1) through (b)(3). However, the procedures must address a more limited set of topics than specified in § 26.27 [Written policy and procedures], the section of Part 26 that deals with policy and procedures for FFD programs generally. Thus, the final rule reduces the scope of the FFD procedures that are required for FFD programs applicable to the individuals listed in § 26.4(f), compared to the scope of the former rule and the proposed rule. This section implements Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.403(b)(1) requires the written procedures to address the methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the privacy of the individual who provides a specimen, procedures for protecting the integrity of the specimen, and procedures for ensuring that the test results are valid and attributable to the

correct individual.

Section 26.403(b)(2) requires the procedures to describe the immediate and followup actions that must be taken if an individual is determined to have: (1) been involved in the use, sale, or possession of illegal drugs; (2) consumed alcohol to excess before or while constructing safety- or security-related SSCs, as determined by a test that accurately measures BAC; (3) attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means; (4) refused to provide a specimen for testing; or (5) had legal action taken relating to drug or alcohol use.

Section 26.403(b)(3) requires the procedures to 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 while constructing safety- or security-related SSCs; or impairment from any cause which in any way could adversely affect the individual's ability to safely and competently perform his or her duties.

The NRC considers the procedures specified in § 26.403(b)(1) to (b)(3) to be the minimum set of procedures necessary to implement an effective FFD program meeting the requirements of Subpart K. Those sections clarify the requirements in the former rule and the proposed rule for FFD policy and procedures by explaining what is meant by the requirements and limiting them to the listed topics. The section satisfies Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 of the rulemaking to improve clarity in the organization and language of the rule. As specified in § 26.401(c), licensees and other entities are free to adopt procedures for other aspects of their FFD programs that are applicable to the individuals listed in § 26.4(f).

Section 26.405 Drug and alcohol testing.

The former rule required reactor construction permit holders to implement a chemical

testing program, including random tests. The proposed rule made the requirement more explicit, by requiring the implementation of a drug and alcohol testing program, including random testing, during construction. The final rule requires pre-assignment, for-cause, post-accident, and followup testing, as discussed with respect to § 26.405(c), but does not require random testing of all individuals who are constructing safety- or security-related SSCs, as discussed with respect to § 26.405(b), if a licensee or other entity implements a fitness monitoring program, as discussed with respect to § 26.406.

The NRC concludes that there is a strong empirical basis for requiring drug and alcohol testing for construction. SAMHSA conducts annual surveys that investigate the prevalence, patterns, and consequences of alcohol and illegal drug use and abuse in the general U.S. civilian population. Its National Household Survey on Drug Abuse (NHSDA) covering the years 2000-2001, for example, indicated that over 23 percent of male construction workers aged 18-24 and over 11 percent of those 25 and older admitted to the use of an illicit drug within the month previous to the survey, while over 75 percent of the 18-24 age group and almost 55 percent of the over 25 group admitted to binge drinking or heavy use of alcohol at least once during the prior month. Because of the relatively small number of female construction workers, the data pertain only to male construction workers. A study based on the results of the SAMHSA NHSDA conducted in 1994 and in 1997 showed that in 1994 15.6 percent of full-time construction workers, ages 18-49, reported current illicit drug use and 17.6 percent reported heavy alcohol use, while in 1997 14.1 percent and 12.4 percent reported such drug and alcohol use, respectively. The report of the 2000 SAMHSA NHSDA stated that “workers in the construction and mining industries reported the highest rates” of heavy alcohol use, illicit drug use, dependence on or abuse of alcohol, and dependence on or abuse of illicit drugs among full time workers aged 18 through 49 in the U.S. labor force. Construction industry groups, such as the Construction Safety and Drug Abuse Executive Roundtable, also have concluded that “drug

abuse continues to be widespread in the construction industry," affecting up to 25 percent of the workforce. Finally, data collected annually through the FFD program performance reports and evaluated by the NRC show a consistent pattern of substantially higher incidence of detections of drugs and/or alcohol in the population of short-term employees, which includes construction workers who seek employment or are employed during outages, who are given pre-access, random, for-cause, and post-event drug and alcohol tests by the FFD programs of reactor licensees, compared to long-term permanent employees at reactors.

To clarify that the drug and alcohol testing requirements under Subpart K are not intended to incorporate all of the requirements in Subparts C [Granting and Maintaining Authorization], E [Collecting Specimens for Testing], F [Licensee Testing Facilities], and G [Laboratories Certified by the Department of Health and Human Services] of Part 26, but at the same time to ensure that the drug and alcohol testing requirements of Subpart K are clear, the final rule clarifies the proposed rule by substantially expanding the description of the program requirements in § 26.405. This section meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.405(a) requires Subpart K FFD programs to provide a means to deter and detect substance abuse. The FFD programs must include drug and alcohol testing that complies with the requirements of § 26.405. The final rule clarifies that if a licensee or other entity complies with the requirements of § 26.405 with respect to drug and alcohol testing, it is not required to meet the drug and alcohol testing requirements in the balance of Part 26.

Section 26.405(b) specifies that if the licensee or other entity elects to impose random testing for drugs and alcohol on individuals who are constructing safety- or security-related SSCs, the random testing must meet the requirements specified in § 26.405(b)(1) through (b)(4). Random testing must—

(1) Be administered in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected.

(2) 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.

(3) Ensure that all individuals in the population that is subject to testing on a given day have an equal probability of being selected and tested.

(4) Provide that an individual completing a test is immediately eligible for another unannounced test.

The random testing requirements in Subpart K are considerably more flexible than the random testing requirements in § 26.31 [Drug and alcohol testing]. These requirements represent those elements of the random testing requirements under § 26.31 that the NRC has concluded are necessary and appropriate for random testing of employees identified in § 26.4(f). They are intended to ensure randomness of selection for testing but also take into account the potentially difficult logistical problems associated with testing at such large and diverse locations. Licensees and other entities who adopt random testing will need, in particular, to develop a system for tracking individuals who are subject to the random testing program to identify when they are physically present and therefore available and eligible for testing. Licensees and other entities may also need to develop programs to ensure that subcontractors who operate independently also implement random testing programs, and it will be necessary for licensees and other entities to conduct audits of subcontractor programs. Section 26.405 provides licensees and other entities flexibility to design their random testing programs to address those problems. For example, the final rule in Subpart K does not specify that random testing must take place at times including weekends, backshifts, and holidays, and at various times during a shift because the construction schedule may not in all cases include

work during those periods. The final rule also provides flexibility for licensees and other entities to determine the number of random tests to be performed annually and the probability that a member of the population that is subject to the FFD program will be selected for random testing. Because of the likely fluctuations in the numbers of reactor construction employees over the course of a year, the NRC cannot specify that the number of random tests performed annually must be equal to at least 50 percent of the population that is subject to the FFD program, as it does under § 26.31. Finally, Subpart K provides licensees and other entities with the flexibility to adopt a fitness monitoring program under § 26.406 to detect and deter substances abuse, rather than conducting random testing of employees identified in § 26.4(f).

Section 26.405(c) specifies that the individuals who are constructing safety- and security-related SSCs shall be subject to drug and alcohol testing under the following four conditions: (1) Before assignment to construct safety- or security-related SSCs; (2) When the licensee or other entity has adequate cause, arising either in response to an individual's observed behavior or physical condition indicating possible substance abuse or after the licensee or other entity has received credible information that an individual is engaging in substance abuse, as defined in § 26.5; (3) Following an accident in which the individual was involved. Post-accident testing should be conducted as soon as practical after an event involving a human error that was committed by an individual specified in § 26.4(f), where the human error may have caused or contributed to the accident. The licensee or other entity is not required to test individuals who were affected by the event but whose actions likely did not cause or contribute to the event. Post-accident testing may involve more than one individual, and should be conducted if the event resulted in either: (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 U.S. Department of Labor standards contained in 29 CFR 1904.7, and subsequent amendments, 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; or (ii) Significant damage to any safety-related SSC of a facility that is required by the Commission's rules and regulations to be described in the site safety analysis report or preliminary or final safety analysis report. Finally, (4) followup testing should be conducted as part of a followup plan to verify an individual's continued abstinence from substance abuse.

The conditions that can lead to drug and alcohol testing of an individual specified in § 26.405(c)(1) through (c)(4) parallel generally the conditions listed in § 26.31(c)(1) through (c)(4), with changes to reflect the different reasons for testing individuals identified in § 26.4(f) under Subpart K and testing individuals at an operating nuclear reactor under Part 26. Thus, pre-assignment testing is limited to those individuals who will construct safety- or security-related SSCs. Because the NRC has concluded that there is no basis to distinguish between for-cause testing under Subpart K and for-cause testing under Part 26 generally, the final rule in Subpart K defines the basis for for-cause testing by a cross-reference to § 26.5 [Definitions] , as does § 26.31(c)(2). Similarly, § 26.405(c)(3)(i) requires post-accident testing for exactly the same significant illness and personal injury situations as required under § 26.31(c)(3)(i). However, the Subpart K post-accident testing requirement that is triggered by property damage is limited to damage to any safety- or security-related SSC of a facility. The NRC recognizes that in the context of reactor plant construction, damage incidents can occur in a number of contexts that are not related to the impairment or potential sabotage bases for FFD programs under Subpart K (e.g., vehicle accidents, injuries to persons not working on safety- or security-related SSCs). Followup testing under § 26.405(c)(4) is defined exactly the same as followup testing under § 26.31(c)(4). In the NRC's view, the purpose of the testing, to verify an

individual's continued abstinence from substance abuse, is exactly the same in both cases. These requirements meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.405(d) specifies that, at a minimum, FFD programs under Subpart K shall test specimens for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol at the cutoff levels specified in this part for testing urine specimens, or comparable cutoff levels if alternate specimens, such as oral fluids, are used for drug screening. The list of substances for which testing must be conducted under Subpart K exactly parallels the list in § 26.31(d)(1). The NRC considers this the minimum set of substances that an effective and adequate FFD program must include for both construction and operation. However, this section does not prohibit Subpart K programs from testing for additional drugs, consistent with the permission in § 26.31(d)(1)(i)(A) for licensees and other entities who are implementing an FFD program for operating plants to test for additional drugs.

The NRC is not prohibiting drug testing of specimens other than urine under Subpart K because it recognizes that there may be circumstances during construction where waiting for the results of urine drug tests could unacceptably delay the assignment of individuals to construct safety- or security-related SSCs. For example, for some construction activities or in some locations, licensees and other entities may rely on craftspersons from a local union hall and may not know in advance which specific individuals will be assigned to work on a particular day. If the union local does not offer pre-employment testing to its members, a licensee or other entity may elect to conduct an oral fluids drug screen, for example, that provides very rapid results, as long as the collection procedures and testing of oral fluids meet the criteria established in § 26.405(e) by protecting the donor’s privacy and the integrity of the specimen, and stringent quality controls are implemented to ensure that test results are valid and

attributable to the correct individual. The NRC does not permit testing of oral fluids for drugs in FFD programs for other licensees and entities who are subject to Part 26 because the window of detection for marijuana use when testing for oral fluids is very short compared to the window of detection for marijuana use when testing urine specimens, and the NRC has a higher expectation that individuals will be trustworthy and reliable, as demonstrated by the avoidance of substance abuse, for the categories of individuals who are subject to Part 26 under the licensees' and entities' FFD program for operating plants. However, the NRC believes that oral fluids drug test results would be adequate to demonstrate that an individual who will be constructing safety- and security-related SSCs is not impaired that day from recent marijuana use or the other substances for which testing is required under § 26.405(d). Permitting testing of alternate specimens under FFD programs for construction is consistent with Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs. This permission is also consistent with § 26.2(c) of the former rule and § 26.3(e)(2) of the proposed rule that required drug and alcohol testing during construction, but did not specify the specimens to be tested.

Section 26.405(d) also requires that urine specimens collected for drug testing must be subject to validity testing. Although § 26.405(d) specifies that urine specimens collected for drug testing must be subject to validity testing and does not further elaborate on the validity testing requirement, the NRC considers the regulatory detail found in § 26.31 to provide useful guidance to licensees and other entities on the agency's expectations. However, Subpart K also provides flexibility to licensees and other entities with respect to this requirement by not specifying that they are required to meet the standards of § 26.31. This section limits the requirement for validity testing to urine specimens because the final rule does not prohibit the use of specimens other than urine for drug testing under Subpart K and scientifically sound and legally defensible means of testing the validity of other types of specimens are not yet available

for some alternate specimens. The requirements in this section meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.405(e) specifies that the specimen collection and drug and alcohol testing procedures of FFD programs under this subpart must protect the donor's privacy and the integrity of the specimen and implement stringent quality controls to ensure that test results are valid and attributable to the correct individual. At the licensee's or other entity's discretion, specimen collections and alcohol testing may be conducted at a local hospital or other facility in accordance with the specimen collection and alcohol testing requirements of 49 CFR Part 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs" (65 FR 41944; August 9, 2001), and subsequent amendments. This section of the final rule is intended to provide licensees and other entities with additional flexibility about the locations where specimen collections and alcohol testing may be carried out and to help ensure that licensees will not be required, before construction can begin, to build specimen collection and alcohol testing facilities at sites that are distant from a current licensee's specimen collection facilities for drug and alcohol testing. This provision is consistent with the former and proposed rules, which also did not require the construction of specimen collection and alcohol testing facilities. This requirement meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.405(f) specifies that testing of urine specimens for drugs and validity, except validity screening and initial drug and validity tests that may be performed by licensee testing facilities, must be performed in a laboratory that is certified by HHS for that purpose, consistent with its standards and procedures for certification. This section requires that urine specimens collected for drug testing must be subject to initial validity and drug testing by the laboratory

because means to attempt to adulterate or substitute a urine specimen are readily available, but does not apply these requirements to drug testing of other specimens for two reasons: (1) Some HHS-certified laboratories may not have the capability to perform tests of alternate specimens, such as oral fluids, or validity testing of alternate specimens, and (2) means for attempting to adulterate or substitute some alternative specimens (e.g., oral fluids) are not readily available. However, any initial drug test performed by a licensee or other entity subject to Subpart K, including tests of alternate specimens, must use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. Urine specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results must be subject to confirmatory testing by an HHS-certified laboratory, except for invalid specimens that cannot be tested. Alternate specimens that yield positive drug test results must be subject to confirmatory testing by a laboratory that meets quality control requirements that are at least as stringent as the requirements those laboratories are required to meet for HHS-certification, such as the accreditation process of the American College of Pathologists. These requirements constitute the general administrative procedures that the NRC considers necessary for drug testing. Licensees and other entities would be allowed to conduct initial testing of urine or alternate specimens at a licensee testing facility, provided that the licensee testing facility staff members possess the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for testing are implemented. However, in parallel with § 26.31, Subpart K requires licensees and other entities to use only HHS-certified laboratories to perform drug testing of urine specimens, except if a licensee testing facility performs initial tests. This requirement is consistent with the former and proposed rules, which also required the use of only HHS-certified laboratories for testing urine specimens for drugs.

Section 26.405(g) requires FFD programs under Subpart K to provide for an MRO

review of positive, adulterated, substituted, and invalid drug and validity test results from confirmatory testing to determine whether the donor has violated the FFD policy, before reporting the results to the individual designated by the licensee or other entity to perform the suitability and fitness evaluations required under § 26.419. This requirement in Subpart K parallels the requirement in § 26.169 [Reporting results] of the final rule. This requirement is an integral component of all Federally-mandated drug and alcohol testing programs, and required by the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs. It is fully consistent with the former and proposed rules, which also followed the HHS Guidelines. This requirement meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.406 Fitness monitoring.

Section 26.406(a) of Subpart K specifies that the requirements in § 26.406 apply only if a licensee or other entity does not elect to subject the individuals specified in § 26.4(f) to random testing for drugs and alcohol under § 26.405(b). The NRC considers fitness monitoring of the individuals who are constructing safety- and security-related SSCs, as specified in § 26.406, to be a means of detecting and deterring substance abuse that can function as effectively as random testing, given the logistical and other issues associated with random testing. Daily monitoring of individuals by trained personnel provides a constant source of information about their fitness, in contrast to the sporadic information provided by random testing. Fitness monitoring can immediately detect situations where for-cause testing is required as well as provide a degree of deterrence comparable to the deterrence provided by the potential for a random test. Subpart K gives a licensee or other entity the flexibility to adopt either random testing under § 26.405, or fitness monitoring under § 26.406, or to implement

both if the licensee or other entity chooses. Neither the former rule nor the proposed rule explicitly required fitness monitoring. However, both listed the performance objective standards section as one of the specific rule sections that an FFD program applicable to individuals involved with the construction of a new reactor plant was required to satisfy. Attainment of the performance objectives clearly implied that licensees and other entities would undertake a program to deter substance abuse and detect impairment. Section 26.406(b) described below contains a similar performance objective. The requirement for fitness monitoring in § 26.406, if a licensee or other entity does not implement random testing of individuals who construct safety- and security-related SSCs, meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.406(b) establishes the performance objective for a fitness monitoring program. It requires licensees and other entities to implement a program to deter substance abuse and detect indications of possible use, sale, or possession of illegal drugs, use or possession of alcohol while constructing safety- or security-related SSCs, and impairment from any cause that if left unattended may result in a risk to public health and safety or the common defense and security. Both the former rule and the proposed rule included a cross-reference to the performance objectives standard. Thus, § 26.406(b) of the final rule extends and clarifies the former and proposed rules.

Section 26.406(c) requires licensees and other entities to establish procedures that fitness monitors shall follow in response to the indications and actions specified in § 26.406(b) and to train the monitors to implement the program. Section 26.406(d) provides licensees and other entities with significant flexibility in determining the number of individuals required to monitor fitness and the procedures they are required to follow, commensurate with the potential risk. Development of fitness monitoring procedures and training of monitors in those

procedures as well as the licensee's or other entity's requirements for program implementation will ensure that fitness monitors know what is meant by the requirement and are informed about the procedures for implementing this requirement.

Section 26.406(d) requires licensees and other entities to ensure that the fitness of individuals who are constructing safety- and security-related SSCs is monitored effectively, commensurate with the potential risk to public health and safety and the common defense and security imposed by the construction activity. To achieve this objective, the rule requires licensees and other entities to consider the number and placement of monitors required, the necessary ratio of monitors to individuals specified in § 26.4(f), and the frequency with which the individuals shall be monitored while performing each construction activity. The NRC does not expect that the individuals designated as fitness monitors will be dedicated solely to the task of fitness monitoring. Licensees and other entities may assign fitness monitoring responsibilities to first-line supervisors, security personnel, and others who are performing other activities for the licensee or other entity while monitoring the fitness of individuals who are constructing safety- and security-related SSCs. In determining the number of such monitors licensees and other entities may need to consider how to ensure that equipment, walls, and other temporary or permanent barriers do not interfere with the monitors' abilities to maintain visual contact with individuals performing the construction activity and whether monitoring will be conducted continuously until completion of the construction activity, continuously only at critical points during a construction activity, once at the beginning of a shift and again after a lunch break, or at a frequency of every few hours on an irregular schedule. Licensees and other entities thus have considerable flexibility in designing their fitness monitoring program. However, they must ensure that the program meets the performance objective stated in § 26.406(b). This requirement is consistent with the requirement in the former rule that FFD programs pertaining to employees at reactor construction sites satisfy former § 26.10(b), calling

for measures for the early detection of persons who are not fit to perform activities within the scope of Part 26.

Section 26.407 Behavioral observation.

Section 26.407 [Behavioral observation] provides that individuals in § 26.4(f) shall be subject to behavioral observation while they are constructing safety- and security-related SSCs at the location where a nuclear power plant is under construction and will be operated. However, if these individuals are subject to a fitness monitoring program under § 26.406, they are not required to be subject to behavioral observation under § 26.407. Thus, this section provides licensees and other entities with the flexibility of subjecting the individuals specified in § 26.4(f) to either fitness monitoring under § 26.406 or to a combination of random drug and alcohol testing under § 26.405 and behavioral observation under § 26.407.

Behavioral observation is an important component of an FFD program because it increases the likelihood that the licensees and other entities who are subject to the rule detect and appropriately address impairment and other adverse behaviors. The individuals listed under § 26.4(e) will be trained in behavioral observation, because § 26.4(e) specifies that they shall be subject to an FFD program that meets all of the requirements of Part 26, except Subparts I and K, and such a program includes behavioral observation training. The individuals who will perform the behavioral observation are specified under § 26.4(e) as including any individual whose duties for the licensees and other entities in § 26.3(c) require him or her to perform the following activities at the location where the nuclear power plant will be constructed and operated: (1) serves as a security officer under NRC requirements; (2) performs quality assurance activities, as specified in Appendix B to Part 50; (4) is designated under § 26.406 by a licensee or other entity to monitor the fitness of the individuals specified in § 26.4(f) (and thus has also received fitness monitoring training); or (5) has responsibility for determining that

inspections, tests, and analyses, or parts thereof, required under 10 CFR Part 52 have been successfully completed. Because of their important oversight responsibilities, these individuals will be subject to an FFD program that meets the requirements for Subparts A through H, N, and O of Subpart 26. In addition to behavioral observation training, they will be subject to random testing at the 50 percent annual rate and a suitable inquiry/employment history check.

Neither the former rule nor the proposed rule explicitly required behavioral observation. However, both listed the performance objective standards section as one of the specific rule sections that an FFD program applicable to individuals involved with the construction of a new reactor plant was required to satisfy, and attainment of the performance objectives clearly implied the use of behavioral observation. The final rule clarifies the requirement and adds flexibility. This requirement is consistent with the requirement in the former rule that FFD programs pertaining to employees at reactor construction sites satisfy former § 26.10(b), calling for measures for the early detection of persons who are not fit to perform activities within the scope of Part 26. Section 26.407 meets Goal 3, to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.409 Sanctions.

Section 26.409 [Sanctions] requires FFD programs under Subpart K to establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.4(f) from being assigned to or performing the duties specified in that section until the licensee or other entity determines that the individual's behavior does not pose a threat to public health and safety or the common defense and security. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 6 to improve clarity in the organization and language of the rule.

The former rule provided for flexibility in the development and application of sanctions by

specifying only that an FFD program applicable to individuals involved in the construction of a new reactor plant should make provision for the imposition of sanctions but did not otherwise specify the level or type of sanctions to be applied. The proposed rule, in § 26.3(e)(3), included an identical provision, also without specifying the level or type of sanctions to be included in the FFD program. By adding explicit criteria for the types of FFD policy violations to which sanctions shall be applied, the final rule clarifies the sanctions provision of the former and proposed rules. This provision in the final rule adds flexibility because it does not require FFD programs under Subpart K to implement the minimum requirements for sanctions in § 26.75 [Sanctions] or to apply the specific procedures for conducting a determination of fitness in § 26.189. Subpart K also allows licensees and other entities the flexibility to assign individuals who violate the FFD policy under Subpart K to other duties at the site not covered by the FFD program, depending on the licensee's assessment of the violation and the other duties involved.

Section 26.411 Protection of information.

Section 26.411(a) requires FFD programs that collect personal information about an individual for the purpose of complying with Subpart K to establish and maintain a system of files and procedures to protect the personal information. It also requires FFD programs to maintain and use such records with the highest regard for individual privacy. This requirement exactly parallels the requirement in § 26.37 [Protection of information] of the final rule pertaining to protection of information under Part 26 generally. The NRC does not believe that any lesser standard of protection can be justified for personal information collected under Subpart K than is required for personal information collected under Part 26 generally. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs, Goal 6 to improve clarity in the organization and language of the rule, and Goal 7 to protect the privacy of individuals.

The final Subpart K rule parallels the requirements in the former rule and in the proposed rule. Both included a requirement that FFD programs applicable to individuals involved with the construction of a new reactor plant make provisions for the protection of information. Section 26.411(a) provides additional detail about the level of protection (the highest regard for individual privacy) required of FFD programs that maintain and use records of personal information. Thus, this final rule provides additional clarity, compared to the former rule or the proposed rule, that the program should achieve the necessary protection through a system of files and procedures.

Section 26.411(b) requires licensees and other entities to obtain a signed consent that authorizes the disclosure of the personal information collected and maintained under Subpart K before disclosing the personal information, except for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.413 [Review process]. These persons include the subject individual or his or her representative, when the individual has designated the representative in writing for specified FFD matters; assigned MROs and MRO staff; NRC representatives; appropriate law enforcement officials under court order; a licensee's or other entity's representatives who have a need to access the information to perform assigned duties, including determinations of fitness, audits of FFD programs, and human resources functions; the presiding officer in a judicial or administrative proceeding that the subject individual initiates; and other persons pursuant to court order. The NRC did not include a reference to § 26.37(b)(7) because it refers to persons deciding matters under another section of Part 26 that Subpart K does not include. Instead, this section adds a new reference to persons deciding matters under review in § 26.413. The requirement to obtain permission to release the personal information to individuals who are not specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.413 is necessary because licensees have misinterpreted the

former requirement as prohibiting them from releasing the personal information under any circumstances. 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 final rule includes the explicit permission for licensees and other entities to release personal information when an individual consents to the release, in writing. This requirement precisely parallels the requirement in § 26.37, except for the differences noted, because the NRC does not believe that any different procedures for handling personal information can be justified for personal information collected under Subpart K than are required for personal information collected under Part 26 generally.

Section 26.413 Review process.

Section 26.413 requires FFD programs under Subpart K to establish and implement procedures for the review of a determination that an individual listed in § 26.4(f) 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. This requirement parallels the one in § 26.39(a) of the final rule. Because the NRC recognizes that much of the construction workforce will be transient and rapidly changing, it is leaving licensees and other entities the flexibility to adopt the additional review procedures found in § 26.39(b) through (e), but is not mandating their adoption by including them in the review process requirements in § 26.413. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 6 to improve clarity in the organization and language of the rule.

The final rule is more explicit than the former rule, which specified only that the FFD program for the reactor construction workforce should make provisions for appeals procedures.

The proposed rule in § 26.3(e)(3) similarly required FFD program for construction to make provisions for procedures for the objective and impartial review of authorization decisions. This final rule more clearly requires FFD programs under Subpart K to establish and implement procedures and more clearly specifies that the procedures are for the review of the facts related to the determination that an individual has violated the FFD policy. However, the basic requirement in this final rule is the same as that in the former rule and the proposed rule. The requirement for an objective and impartial review establishes the same criteria for the review as did the proposed rule, which also mandated an impartial and objective review.

Section 26.415 Audits.

Section 26.415 [Audits] establishes audit requirements for Subpart K FFD programs. Section 26.415(a) requires licensees and other entities to ensure that audits are performed to assure the continuing effectiveness of the FFD program, including FFD program elements that C/Vs provide, and the FFD programs of C/Vs that are accepted by the licensee or other entity. This requirement parallels the audit requirement in § 26.41(a) of the final rule. The agency has not identified any circumstances relating to the reactor construction workforce that would support different auditing requirements for Subpart K FFD programs than for FFD programs under the other subparts of Part 26. The criterion to be applied for each audit program is that it must assure the continuing effectiveness of the FFD program. Although the former rule did not contain a requirement for audits of the FFD program at reactor construction sites, the proposed rule referred explicitly to § 26.41[Audits and corrective action] as one of the requirements to be included in the FFD program under Subpart K. Thus, § 26.415 extends and clarifies the requirement in the proposed rule, meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs, and satisfies Goal 6 to improve clarity in the organization and language of the rule.

Section 26.415(b) requires each licensee and other entity who implements an FFD program under Subpart K to ensure that these programs are audited at a frequency that ensures their continuing effectiveness and that corrective actions are taken to resolve any problems identified. The section also provides that licensees and entities may conduct joint audits, or accept audits of C/Vs conducted by others, so long as the audit addresses the relevant services of the C/V. The NRC expects that in determining the frequency of audits, licensees and other entities will consider the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, previous audit findings, and lessons learned. The requirement is intended to promote performance-based rather than compliance-based audit activities. By allowing joint audits, the final rule creates additional flexibility for Subpart K FFD programs.

Section 26.415(c) provides that licensees and other entities who implement FFD programs under Subpart K need not audit the HHS-certified laboratories or specimen collection and alcohol testing services that meet the requirements of 49 CFR Part 40, “Procedures for Department of Trasnporation Workplace Drug and Alcohol Testing Programs” (65 FR 41944, August 9, 2001) upon which licensees and other entities may rely to meet the drug and alcohol testing requirements of Subpart K. Because the DOT conducts audits of collection sites that the agency's grantees use, the NRC has concluded that audits of those sites when they are used by NRC licensees and other entities are unnecessary.

Section 26.417 Recordkeeping and reporting.

Section 26.417(a) of the final rule provides that FFD programs shall ensure that records pertaining to the administration of the program, which may be stored and archived electronically, are maintained so that they are available for NRC inspection purposes and for any legal proceedings resulting from the administration of the program. This recordkeeping

provision provides more extensive detail than the equivalent recordkeeping sections of the former rule or the proposed rule, both of which provided only that the FFD program for the reactor construction workforce should make provisions for recordkeeping. This final rule provides notice that records may be stored and archived electronically, which clarifies the requirement and provides flexibility to licensees and other entities. This rule also incorporates standard language pertaining to the availability of records for NRC inspection purposes and for any legal proceedings resulting from the administration of the program. These provisions are inherent to the NRC's recordkeeping requirements. While adding clarity, they do not significantly change the recordkeeping requirement from that in the former or proposed rule. Both the former rule and the proposed rule contained an explicit requirement for recordkeeping by the FFD program applicable to reactor construction workers. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.417(b) requires licensees and other entities that implement FFD programs under Subpart K to make the reports described in § 26.417(b)(1) and (b)(2). Section 26.417(b)(1) requires reports to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to Subpart K. This provision also specifies that these events must be reported under Subpart K, rather than under the provisions of 10 CFR 73.71 [Reporting of safeguards events]. Section 26.417(b)(2) requires annual program performance reports for the FFD program. The former rule contained detailed reporting requirements similar to those in the final rule. In addition, the NRC considers the reporting of acts that cast doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD

program that may permit undetected drug or alcohol use or abuse by individuals subject to Subpart K, as well as annual program performance reports, to be clearly logical and necessary components of the program and outgrowths of the recordkeeping requirements.

Section 26.419 Suitability and fitness evaluations.

Section 26.419 requires licensees and other entities who implement FFD programs under Subpart K to develop, implement, and maintain procedures for evaluating whether to assign individuals to the duties specified in § 26.4(f). These procedures must provide reasonable assurance that such individuals are fit to safely and competently perform their duties and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse. This section provides flexibility for Subpart K programs to develop procedures for determining suitability. The requirement that licensees and other entities develop, implement, and maintain procedures for evaluating whether to assign individuals to the duties specified in § 26.4(f) is necessary to enable licensees and other entities to implement Subpart K. These procedures will allow licensees, other entities, and the individual employees to know who the Subpart K requirements cover. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Although neither the former rule nor the proposed rule contained an explicit requirement for suitability and fitness evaluations, each contained a cross-reference to the general performance objectives sections of their respective rules (§ 26.10 of the former rule and § 26.23 of the proposed rule). Section 26.10 required the FFD programs applicable to reactor construction workers to provide reasonable assurance that personnel would perform their tasks in a reliable and trustworthy manner and that they are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way would affect

their ability to safely and competently perform their duties. Section 26.23 of the proposed rule used language similar to that in this final rule, requiring FFD programs to provide reasonable assurance that individuals who are subject to Part 26 are trustworthy and reliable, as demonstrated by the avoidance of substance abuse, and to provide reasonable assurance that individuals who are subject to Part 26 are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely impairs their ability to safely and competently perform their duties.

Subpart L – [Reserved]

Subpart M – [Reserved]

Subpart N – Recordkeeping and Reporting Requirements

As a result of the reorganization of the proposed rule, the NRC has moved the provisions from Subpart J of the proposed rule to a new Subpart N of the final rule. The final rule includes minor clarifications of the language of the proposed rule that are discussed with respect to those sections. The NRC has also made more substantive changes to the proposed rule in § 26.711(c) and (d). Otherwise, the provisions in this subpart have been adopted as proposed without change.

Section 26.709 Applicability.

The NRC has added § 26.709 to the final rule to specify the licensees and other entities to whom the requirements of this subpart apply.

Section 26.711 General provisions.

The NRC has added § 26.711 to the final rule to define general requirements related to

recordkeeping and reporting under Part 26.

Section 26.711(a) of the final rule establishes a requirement that licensees and other entities must maintain records and submit certain reports to the NRC, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. In addition, this section requires that licensees and other entities retain the records required under this part for either the periods that are specified in Subpart N 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 clarifies the language of the rule and 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).

The NRC has added § 26.711(b) to the final rule 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. This provision recognizes that most records are now stored electronically and must be protected to ensure the integrity of the data. The requirements are consistent with related requirements in the access authorization orders issued to nuclear power plant licensees dated January 7, 2003. Therefore, these requirements meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56 [Personal access authorization requirements for nuclear power plants], as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

In the final rule, the NRC has added a new provision in § 26.711(c). This provision requires licensees and other entities to inform individuals of the right to review and correct the records maintained about the individual under this part and imposes a requirement on licensees

and other entities to ensure that the information they maintain and share with other licensees and entities is correct and complete. The NRC added this provision to provide further assurance that individuals who are subject to an FFD program under this part are not unjustly or inaccurately portrayed as having violated FFD requirements in any written documentation that licensees and other entities rely on when making authorization decisions. This provision meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26. This provision is also meets Goal 4 of this rulemaking to improve consistency between this rule and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

The NRC has also added § 26.711(d) to the final rule to require licensees and other entities to ensure that only correct and complete information about individuals is retained and shared. This provision specifies that licensees and other entities shall correct or augment shared information contained in the records if this information changes or new information is developed. Also, if the changed or new information has implications for adversely affecting an individual's eligibility for authorization, the final rule requires that the licensee or other entity who discovers the incorrect information or developed new information shall inform the reviewing official of the updated information. The NRC has added this provision to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26. This provision also meets Goal 4 of this rulemaking to improve consistency between this rule and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Section 26.713 Recordkeeping requirements for licensees and other entities.

Section 26.713 of the final rule amends former § 26.71 [Recordkeeping requirements].

Former § 26.71(d), which established requirements for FFD program performance reports, is retained in § 26.717 [Fitness-for-duty program performance data], a separate section that focuses only on those reports. Section 26.713 retains but amends former § 26.71(a) through (c) and adds other requirements that are interspersed throughout the former rule. The NRC has made these changes to meet Goal 6 of this rulemaking 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.

Section 26.713(a) of the final rule requires licensees and other entities to retain certain records related to authorization decisionmaking 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 agency has added the requirement to retain records until the completion of all related legal proceedings at the suggestion of stakeholders during the public meetings discussed in Section I.D. The stakeholders noted that some legal proceedings involving records of the type specified in the paragraph have continued longer than the 5 years that the former rule required these records to be retained and that adding a requirement in the final rule to retain the records until all legal proceedings are complete protects an individual's right to due process under the rule. This provision is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.713(a)(1) amends former § 26.71(a). Former § 26.71(a) required 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 final rule updates the terminology used in the former paragraph for consistency with the revised language used throughout the rule. For example, the paragraph refers to "self-disclosures," "employment histories," "suitable inquiries," and "granting authorization," but retains the intent of

the former paragraph. The NRC has made the changes in terminology for the reasons discussed with respect to §§ 26.61 [Self-disclosure and employment history] and 26.63 [Suitable inquiry]. In addition, the agency has updated the former cross-reference to § 26.27(a) to reflect the new organization of the rule.

Section 26.713(a)(2) amends former § 26.71(b). Former § 26.71(b) required licensees to retain records that are related to positive drug test results that the MRO has confirmed. The final rule revises the former requirement by mandating that licensees and other entities retain records related to any violation of the FFD policy, which includes confirmed positive drug and alcohol test results. This change ensures 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 decisionmaking process specified in § 26.69 [Authorization with potentially disqualifying fitness-for-duty information].

The NRC has added § 26.713(a)(3) to the final rule to require licensees and other entities to retain records that are related to the granting and termination of an individual's authorization. This provision ensures that licensees and other entities who may be considering granting authorization to an individual under Subpart C [Granting and Maintaining Authorization] can determine which category of authorization requirements in Subpart C applies to the individual, based upon the length of time that has elapsed since the termination of the individual's last period of authorization and whether it was terminated favorably. The new section discusses the categories of authorization requirements with respect to §§ 26.55 [Initial authorization], 26.57 [Authorization update], 26.59 [Authorization reinstatement], and 26.69 [Authorization with potentially disqualifying FFD information].

The NRC has added § 26.713(a)(4) to the final rule to require licensees and other entities to retain records that are related to any determination of fitness that was conducted

under § 26.189 [Determination of fitness]. The final rule, with respect to the proposed rule, clarifies that the records to be retained include any recommendations for treatment and followup testing plans. This provision ensures 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 decisionmaking process specified in § 26.69. In addition, if an individual who is subject to followup testing and a treatment plan transfers to another FFD program, the reviewing official and SAE of the receiving FFD program, which takes responsibility for implementing the testing and treatment plans, are required to have access to this information under § 26.69(e).

Section 26.713(b)(1) and (b)(2) of the final rule requires 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. These paragraphs retain the 3-year recordkeeping requirements of the former rule in §§ 26.21(b) and 26.22(c) for training records, and § 26.80(c) for audit findings and corrective action records.

Section 26.713(c) of the final rule amends former § 26.71(c). Former § 26.71(c) required licensees to retain records related to any individual who was made ineligible for authorization for 3 years or longer under former § 26.27 [Management actions and sanctions to be imposed] until the Commission terminates each license under which the records were created. However, the final rule requires 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 requirement to retain records related to 5-year denials of authorization is consistent with the more stringent sanctions established in § 26.75(c), (d), and (e)(2), in which the NRC has eliminated the sanction of a 3-year denial of authorization, as discussed with respect to those paragraphs.

The 40-year retention requirement is 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 does not mean that individuals whose authorizations were 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 ensures that the records of the 5-year and permanent denials are available, should the individual seek authorization from another licensee or other entity. This amendment is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.713(d) of the final rule replaces the recordkeeping requirement in former § 26.20 [Written policy and procedures]. This paragraph requires licensees and other entities to retain superseded FFD policies and procedures 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. The NRC has increased the required period for retaining superseded materials 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 requirement to retain the policy and procedures related to any matter under legal challenge until the matter is resolved ensures that the materials remain available if 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. This provision is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.713(e) of the final rule amends the requirement in former § 26.23(a) pertaining to the retention of written agreements for the provision of FFD program services. This provision requires licensees and other entities to retain the written agreement for the life of

the agreement (as in the former rule), or until completion of all legal proceedings related to an FFD violation that involved the services, whichever is later. This requirement ensures that the materials remain available should an individual, the NRC, a licensee, or another entity who is subject to the rule require access to them in a legal or regulatory proceeding. This amendment is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 3 to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.713(f) to the final rule 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 § 26.31(b)(1)(i), 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. This requirement is consistent with the last phrase of former Section 2.6(c) in Appendix A to Part 26, which required 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 required period during which these records must be maintained is 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 if an individual, the NRC, a licensee, or another entity who is subject to this rule requires access to them in a legal or regulatory proceeding. However, the final rule establishes 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. This new provision is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 3 to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.713(g) to the final rule to require licensees and other entities

to retain records of the certification, provided by a qualified forensic toxicologist, as required under § 26.31(d)(1)(i) and (d)(3)(iii)(C), of the scientific and technical suitability of any assays and cutoff levels used for drug testing that this part does not address. This provision requires 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 this part does not require testing, uses more stringent cutoff levels than those specified in this part, or until the completion of all related legal proceedings, whichever is later. This new requirement ensures that the NRC has access to the records for inspection purposes and that the records remain available if an individual, the NRC, a licensee, or another entity who is subject to this rule requires access to them in a legal or regulatory proceeding. This provision is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.715 Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services.

The NRC has added § 26.715 to the final rule to group together in one section the recordkeeping requirements that apply to collection sites, licensee testing facilities, and HHS-certified laboratories.

Section 26.715(a) of the final rule retains the requirement in former Section 2.7(n) in Appendix A to Part 26. This provision mandates that collection sites, HHS-certified laboratories and licensee testing facilities must maintain documentation of all aspects of the testing process for at least two years. The final rule includes collection sites within this provision because licensee testing facilities and collection sites may not be co-located, as was typically the case when the former rule was first published. This section retains the provision in former

Section 2.7(n) that the two-year period may be extended upon written notification by the NRC or any licensee or other entity for whom services are being provided. The final rule also adds a requirement to retain the documentation until completion of all legal proceedings related to an FFD violation to ensure that the records remain available if 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. This change is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 3 to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.715(b)(1) through (b)(14) to the final rule to list in a single paragraph the documents that collection sites, licensee testing facilities, and HHS-certified laboratories must retain. Specifically, those documents include personnel files of individuals who are no longer working at a collection site, licensee testing facility, or HHS-certified laboratory; on 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 former rule in §§ 26.20 and 26.71(a) and 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 of Appendix A to Part 26. The final rule groups them together in a single paragraph to make them easier to locate within the rule, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.717 Fitness-for-duty program performance data.

The NRC has added § 26.717 to the final rule to amend the requirements in former § 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, this paragraph requires licensees and other entities to submit program performance data to the NRC every 12 months, rather than every 6 months. The NRC has made the additional conforming changes described below to former § 26.71 for consistency with other revisions to the rule.

Section 26.717(a) of the final rule retains the requirement in former § 26.71(d) that each FFD program subject to Part 26 must collect and compile FFD performance data.

Section 26.717(b)(1) through (b)(8) of the final rule amends the second sentence of former § 26.71(d). The provision specifies the FFD program performance data that a licensee or other entity must report, including the random testing rate, the drugs for which testing is conducted and their 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. With respect to the proposed rule, the final rule clarifies § 26.717(b)(2) to be consistent with the changes the NRC has made to procedures for dilute specimens, as discussed with regard to § 26.163(a)(2). This paragraph is identical to the requirements of the former provision with two exceptions: (1) the final rule requires reporting the number of subversion attempts by type, and (2) does not require a list of events reported during the reporting period.

Concerning the first exception, the final rule adds a requirement for licensees and other entities to report the number of subversion attempts by type. This new requirement is 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 §§ 26.31(d)(3)(i) and 26.75(b). Although this information is available to NRC inspection personnel at each site, it would be costly and an inefficient use of resources for inspectors to aggregate and report it annually. Under the former rule, licensees typically reported subversion attempts they detected under the requirement to summarize "events reported" in former § 26.71(d). Therefore, the NRC expects that the reporting requirement imposes minimal additional burden. The agency has added this requirement to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Second, the final rule eliminates the former requirement to include the number of events reported to the NRC during the reporting period. The NRC eliminated the former reporting requirement because it has access to this information through other avenues and reporting it twice is unnecessary. Eliminating this requirement meets Goal 5 of the rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.717(c) of the final rule amends the portions of former § 26.71(d) that required licensees and other entities to analyze the FFD program performance data semiannually. Instead, this provision requires licensees and other entities to analyze FFD program performance data annually and retains the requirement that actions must be taken to correct program weaknesses. NRC experience in reviewing FFD program performance reports since it first promulgated the rule has shown that reporting twice per year is unnecessary to ensure the continuing effectiveness of FFD programs. Therefore, the final rule relaxes the semiannual analysis and reporting requirement, consistent with Goal 5 of the rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. Furthermore, the provision requires licensees and other entities to retain for 3 years records of the data, analysis, and corrective actions taken, which is the same as the former requirement in § 26.71(d). However, the rule adds a requirement to retain the documentation until completion of any legal

proceedings related to an FFD violation to ensure that the records remain available if an individual, the NRC, a licensee, or another entity who is subject to this rule requires access to them in a legal or regulatory proceeding. The agency has added this requirement to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.717(d) of the final rule retains the last sentence of former § 26.71(d). The former provision required any licensee who temporarily suspends an individual's authorization or takes administrative actions on the basis of an initial positive marijuana or cocaine drug test result (under the provisions of former § 26.24(d)) to 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 final rule continues to require that the report include the number of administrative actions taken against individuals for the reporting period. However, the agency has eliminated the term "temporarily suspend" from the provision and replaced it with the term "administratively withdraw authorization," in response to stakeholder requests at the public meetings discussed in Section I.D. 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, has eliminated the inaccurate phrase from the final rule. The agency made this change to meet Goal 6 of the rulemaking relating to improving clarity in the language of the rule.

Section 26.717(e) of the final rule amends portions of former § 26.71(d). It requires licensees and other entities to submit the annual summary to the NRC by March 1 of the following year, rather than the former requirement to provide a semiannual summary within 60 days of the end of each six-month reporting period. The agency made this change for consistency with the requirement in § 26.717(c) to submit the report annually, as discussed with respect to that paragraph, and to meet Goal 5 of the rulemaking to improve Part 26 by

eliminating or modifying unnecessary requirements.

Section 26.717(f) of the final rule retains the requirement in former § 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.

The NRC has added § 26.717(g) to the final rule to require that C/Vs who maintain an approved drug and alcohol testing program must submit to the NRC the same program performance data that are required from licensees and other entities who are subject to the final 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 requirement is necessary because the final rule applies directly to C/Vs who maintain licensee-approved programs, rather than applying only to licensees under the former rule, as discussed with respect to § 26.3(d). The agency has added this requirement to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.719 Reporting requirements.

The NRC has added § 26.719 to the final rule to replace former § 26.73 and combines it with former Section 2.8(e)(4), (e)(5), and (e)(6) in Appendix A to Part 26. The final rule groups into one section reporting requirements that are interspersed throughout the former rule to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC added § 26.719(a) to the final rule to introduce the section, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. This provision specifies the categories of significant events that licensees and other entities must 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 paragraph retains the requirement in former § 26.73(c) that significant events must be reported under this section,

rather than under the provisions of 10 CFR 73.71 [Reporting of safeguards events].

Section 26.719(b) of the final rule reorganizes and amends former § 26.73(a)(1), (a)(2), and (b), consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. Paragraph 26.719(b) retains the requirement in former § 26.73(b) that notifications of events must be made to the NRC Operations Center within 24 hours of their discovery. However, the final rule presents this requirement at the beginning of the paragraph to clarify that it applies to all of the events that are listed in the paragraph.

Section 26.719(b)(1) amends former § 26.73(a)(1). The former provision required licensees to report the sale, use, or possession of illegal drugs within a protected area. The final rule adds a requirement for licensees and other entities also to report the consumption or presence of alcohol in a protected area. This change is consistent with the NRC's increased concern with the adverse effects of alcohol abuse on safe performance, as discussed with respect to § 26.75(e). The agency has made the change for consistency with the performance objective in § 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. This change also meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, as the consumption or presence of alcohol in a protected area constitutes a significant programmatic failure in achieving this performance objective.

Section 26.719(b)(2) amends former § 26.73(a)(2). Former § 26.73(a)(2) required 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 test results for such persons; involving the use of alcohol within the protected area; or resulting in a determination of unfitness for scheduled work because of the consumption of alcohol. The final rule expands the former reporting requirement to include SSNM transporter personnel and FFD

program personnel. The NRC has made this change to ensure that it 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. The agency's change meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.719(b)(2)(i) retains former § 26.73(a)(2)(i). The provision requires licensees and other entities to report any acts by the subject individuals that involve the use, sale, or possession of a controlled substance.

Section 26.719(b)(2)(ii) combines and amends former § 26.73(a)(2)(ii) and (a)(2)(iv). The former section required licensees and other entities to report any confirmed positive test results for such persons and any acts by the subject individuals that result in a determination of unfitness for scheduled work because of the consumption of alcohol, respectively. The final rule amends the former requirements by mandating that licensees and other entities 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 § 26.5 [Definitions]). This change is consistent with two other changes to the rule: (1) the addition of validity testing requirements to the final rule, as discussed with respect to § 26.31(d)(3)(i), and (2) the addition of new requirements in Subpart D [Management Actions and Sanctions to be Imposed] that impose the same sanctions for confirmed positive alcohol test results as those required for confirmed positive drug test results, as discussed with respect to § 26.75(e). Therefore, the final rule requires licensees and other entities to report confirmed positive drug test results, any other acts to subvert or attempt to subvert the testing process, and confirmed positive alcohol test results for these individuals.

Section 26.719(b)(2)(iii) amends former § 26.73(a)(2)(iii). The former provision required licensees and other entities to report any events involving the consumption of alcohol within the

protected area by the subject individuals. The final rule adds the requirement to report any acts involving the consumption of alcohol while performing the duties that require these individuals to be subject to this part. This change is consistent with the addition of SSNM transporters and FFD program personnel to this paragraph, as discussed with respect to § 26.719(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 § 26.719(b)(2) while they are performing the duties specified in § 26.4 at any location.

Section 26.719(b)(3) establishes 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 acts that could fit this definition and be of concern to the NRC, the final rule does not specify the acts that licensees and other entities must report. However, such intentional acts may include, but are not 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 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 the FFD program uses to randomly select individuals for testing to ensure that specific individuals are not selected.

The intentional acts that this final rule requires licensees and other entities to report could involve any aspect of the operations of the FFD program and the testing process.

The final rule adds this reporting requirement because of other changes to the final rule that permit licensees and other entities to rely on other Part 26 programs to a much greater extent than under the former requirement. The final rule permits 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 requires 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 can take corrective actions, if necessary. The agency has made this change to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.719(b)(4) to the final rule 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 the duties that require them to be subject to the FFD program. In Item 10.1 of NUREG-1385, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions," the NRC emphasized that it expects licensees to exercise prudent judgment in determining whether to report unusual situations and that the significant events the licensees must report are not limited to the examples contained in the rule. However, the NRC understands that licensees have not reported many significant events that would be useful for formulating public policy or that the NRC should respond to in a

timely fashion because licensee management decided not to do so unless the rule specifically required this reporting. Therefore, this final rule adds § 26.719(b)(4) to clarify that significant events and programmatic failures are not limited to those listed in § 26.719(b), but include any programmatic failures or weaknesses that potentially could permit substance abuse to be undetected. The agency has made this change to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.719(c) of the final rule reorganizes and amends former requirements for reporting errors in drug and alcohol testing, consistent with Goal 6 of the rulemaking to improve clarity in the organizational of the rule. The final rule retains the former requirements for licensees and other entities to investigate and take corrective actions for drug and alcohol testing errors in §§ 26.137(f) and 26.167(g) for licensee testing facilities and HHS-certified laboratories, respectively, but moves the reporting requirements to this section.

Section 26.719(c)(1) updates the portion of former § 2.8(e)(4) in Appendix A to Part 26 that mandated that licensees and other entities must report within 30 days of completing an investigation any testing errors or unsatisfactory performance in performance testing at either a licensee testing facility or an HHS-certified laboratory. This section amends the former requirement by specifying that the report of the incident must describe the corrective actions taken or planned. Although licensees and other entities have consistently described corrective actions in such reports, the agency has added this new requirement to meet Goal 6 of the rulemaking to improve clarity in the language of the rule.

In addition, this section adds cross-references to other sections of the final rule that define processes that may also result in the identification of errors, including the reviews required under § 26.39 [Review process for fitness-for-duty policy violations] and § 26.185 [Determining a fitness-for-duty policy violation]. In the original rule, the NRC intended 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 change, consistent with Goal 6 of the rulemaking to improve clarity in the language of the rule, clarifies that the requirement to investigate, correct, and report errors is not limited only to errors identified through blind performance testing in licensee testing facilities and HHS-certified laboratories but also applies to errors identified through any means.

Section 26.719(c)(2) amends the portion of former Section 2.8(e)(5) in Appendix A to Part 26 that required licensees to promptly notify the NRC if a false positive error occurs on a blind performance test sample. This section replaces the former requirement that the report must be made “promptly” with one to report the false positive error within 24 hours of the discovery. The agency has made this change as a result of the public meetings discussed in Section I.D, during which the stakeholders noted that the term “promptly” is vague. Therefore, the final rule clarifies the former requirement by establishing a 24-hour time limit for the notification, consistent with Goal 6 of this rulemaking to improve clarity in the language of the rule.

The rule establishes 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 and/or attempted to subvert the testing process. HHS may decertify a laboratory as a result of false positive test results. The 24-hour time limit ensures that the NRC can quickly notify HHS of the problem so that HHS may initiate the applicable steps required under its 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 a licensee or other entity has submitted. The agency has established the 24-hour

time limit to meet Goal 7 of the rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

The NRC has added § 26.719(c)(3) to the final rule to require licensees and other entities to report any false negative errors identified through quality assurance checks of validity screening tests within 24 hours of the discovery if the licensee or other entity uses these tests for validity screening at a licensee testing facility. This reporting requirement ensures that the NRC is aware of any testing failures, so that other Part 26 programs that rely on the tests 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 tests 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 agency has added this requirement to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

The final rule does not require licensees and other entities to report false positive errors identified through quality assurance checks of validity screening tests for two reasons. First, other provisions of the rule 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 § 26.75(h). Second, donors are protected from the adverse consequences of false positive validity screening test results because these specimens are forwarded to an HHS-certified laboratory for initial and confirmatory testing, if required, before a licensee or other entity is permitted to act, as discussed with respect to § 26.137(c). Therefore, reporting of false positive errors is unnecessary to protect the interests of either donors or the public.

The NRC has added § 26.719(d) to the final rule to require licensees and other entities to document, trend, and correct nonreportable FFD issues that identify programmatic

weaknesses under the licensee's or other entity's corrective action program. The final rule includes 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 final rule adds these requirements for consistency with Criterion XVI in Appendix B to 10 CFR Part 50 [Domestic licensing of production and utilization facilities] and to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

This section also requires licensees and other entities to document, trend, and correct any programmatic weaknesses in a manner that protects individuals' privacy. For example, this section prohibits licensees and other entities from documenting a single confirmed positive, adulterated, substituted, or invalid drug test result in the corrective action program, because such documentation, along with other cues in the work environment, may permit any individual who has access to the corrective action system easily to identify the donor. However, under the final rule, the NRC expects licensees and other entities to document, trend, analyze, and take corrective actions for an increase in the rate of confirmed positive, adulterated, substituted, or invalid 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 or some other factor. The agency has added the requirement to protect individuals' privacy within the corrective action program to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Subpart O – Inspections, Violations, and Penalties

As a result of the reorganization of the proposed rule, the provisions contained in Subpart K of the proposed rule have been moved to Subpart O of the final rule. The NRC received no public comment on Subpart O, and the final rule adopts the provisions in Subpart O

as proposed without change.

The NRC added Subpart O to the final rule to combine into one subpart former §§ 26.70 [Inspections], 26.90 [Violations], and 26.91 [Criminal penalties], consistent with Goal 6 of the rulemaking to improve clarity in the organization of the rule, by grouping related sections into one subpart. Section 26.821 [Inspections] retains the requirements in former § 26.70. Section 26.823 [Violations] retains the requirements in former § 26.90. Section 26.825 [Criminal penalties] retains the requirements in former § 26.91.

The NRC has deleted Appendix A to Part 26 "Guidelines for Drug and Alcohol Testing Programs" in its entirety and has incorporated its requirements into Subparts E, F, and G.

VII. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is amending 10 CFR Part 26 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule are subject to criminal enforcement.

VIII. 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.

IX. 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 revisions to improve the organization and readability of the former language of the paragraphs being revised.

X. 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 FFD programs, that would apply to the requirements 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 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 rule does, and lacks 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 provisions of this rule to meet the objective of comprehensive fatigue management.

XI. 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 is not 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 final rule amends 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 HHS Guidelines and other Federal drug and alcohol testing programs (e.g., those required by 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 of 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 rights and other rights (including due process) of individuals who are subject to 10 CFR Part 26.

It also grants, 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 a petition for rulemaking (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 rule continues 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.

This rule does not significantly increase the probability or consequences of an accident. No changes have been 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 have been 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 this action.

The primary alternative to this action is 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 NRC received no comments on this environmental assessment.

The determination of this environmental assessment is that there will be no significant environmental impact from this action.

XII. Paperwork Reduction Act Statement

The final 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.). These requirements were approved the OMB, approval number 3150-0146.

The burden to the public for these information collections is estimated to average 113.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T-5 F52), 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.

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.

XIII. Regulatory Analysis

The NRC has prepared a final Regulatory Analysis on this regulation. The final regulatory analysis was prepared under the NRC's Regulatory Analysis Guidelines (RA Guidelines), NUREG/BR-0058, Revision 4, dated September 2004. The 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 rule's provisions addressing worker fatigue was performed. A description of each of these three elements is discussed below. Single copies may be obtained from the contact listed above under the FOR FURTHER INFORMATION CONTACT 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 $129 million–$204 million (using 7 percent and 3 percent real discount rates), consisting of $2 million in one-time costs and $10 million in annual net savings. The worker fatigue portions of the final rule are estimated to cost industry $573 million–$898 million net present value (using

the 7 percent and 3 percent real discount rates, respectively), consisting of $12 million in one-time costs and $41 million in annual net costs. The net present value of the entire rule, including both the worker fatigue and drug and alcohol testing portions, is estimated to be a cost to industry of $444 million - $694 million (using 7 percent and 3 percent real discount rates), which consists of $14 million in one-time costs and $32 million in annual costs. In addition, the rule is estimated to be a cost to the NRC of $665,000–$1,025,000 net present value (using 7 percent and 3 percent real discount rates), consisting of $28,000 in one-time costs and $47,000 in annual net costs.

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 Regulatory Analysis. The basic analysis measures the incremental impacts of the 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 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 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 change in addition to the aggregate analysis of the entire rulemaking to determine whether this change should be aggregated with the other 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 regulatory analysis.

C. Dissaggregation of Worker Fatigue Provisions

Section 4.1.4.2 of the Regulatory Analysis summarizes the division of costs and savings of the fatigue management portions of the rule, in comparison with the rest of the rule. The worker fatigue portions of the rule are estimated to cost industry $573 million–$898 million net present value (using the 7 percent and 3 percent real discount rates, respectively), consisting of $12 million in one-time costs and $41 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 fatigue management requirements in the aggregate as a courtesy to stakeholders in Section 4.1.4.2 of the Regulatory Analysis.

XIV. Regulatory Flexibility Act Certification

As required by the Regulatory Flexibility Act, as amended, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule affects only licensees authorized to operate nuclear power reactors; licensees authorized to possess, use, or transport formula quantities of SSNM; corporations who obtain certificates of compliance or approved compliance plans under Part 76 involving formula quantities of SSNM; combined license holders; holders of construction permits; combined license and construction permit holders and combined license and construction permit applicants with authorization to construct; and 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).

XV. Backfit Analysis

The rule constitutes 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 Backfit Analysis is included in the 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.

A. Consideration of Fuel Fabrication Facilities and Gaseous Diffusion Plants

The backfit provision of 10 CFR 70.76 applies to currently licensed fuel fabrication facilities. Although gas centrifuge facilities are licensed under Part 70, these facilities have not been considered in the analysis because NRC has not granted authorization to possess formula quantities of SSNM at these facilities. These facilities have been considered in the aggregate backfit analysis. The planned mixed-oxide fuel fabrication facility also would 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 applies to gaseous diffusion plants, there are no backfit impacts because the

gaseous diffusion plants certified 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 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 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 analysis. Exhibit 4-16 of the 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) and § 70.76(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 $14 million and the annual net costs would be $42 million, resulting in a net present value cost of $582 million–$911 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 FFD rule, considered in the aggregate, constitutes 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 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 17 backfits with reasonable indications that the costs associated with the backfit may be disproportional to the safety benefit attributable to the change. The NRC determined that all of the 17 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 17 backfits were determined to be necessary to meet the objectives of the rule is described in Section 4.4.2 of the Regulatory Analysis.

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XVII. 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.

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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) Licensees who are authorized to operate a nuclear power reactor under 10 CFR 50.57, and holders of a combined license under 10 CFR part 52 after the Commission has made the finding under 10 CFR 52.103(g) shall comply with the requirements of this part, except for subpart K of this part. The FFD program must be implemented before the receipt of special nuclear material in the form of fuel assemblies.

(b) Licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under part 70 of this chapter, and any corporation, firm, partnership, limited liability company, association, or other organization who 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 shall comply with

the requirements of this part, except for subparts I and K of this part.

(c) Combined license holders (under part 52 of this chapter) before the Commission has made the finding under § 52.103(g), combined license applicants who have received the authorization to construct under § 50.10(e)(3) of this chapter, construction permit holders (under part 50 of this chapter), and construction permit applicants who have received the authorization to construct under § 50.10(e)(3) shall comply with the requirements of this part, except subpart I.

(d) Contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that the licensees and other entities specified in paragraphs (a) through (c) of this section rely on those C/V FFD programs or program elements to meet the requirements of this part, shall comply with the requirements of this part.

(e) This part does not apply to either spent fuel storage facility licensees or non-power reactor licensees who possess, use, or transport formula quantities of irradiated SSNM.

§ 26.4 FFD program applicability to categories of individuals.

(a) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and perform the following duties shall be subject to an FFD program that meets all of the requirements of this part, except subpart K of this part:

(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 (SSCs) 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) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and who do not perform the duties described in paragraph (a) of this section shall be subject to an FFD program that meets all of the requirements of this part, except § 26.205 and subpart K of this part.

(c) All persons who are required by a licensee in § 26.3(a) to physically report to the licensee's Technical Support Center or Emergency Operations Facility by licensee emergency plans and procedures shall be subject to an FFD program that meets all of the requirement of this part, except § 26.205 and subpart K of this part.

(d) Any individual whose duties for the licensees and other entities in § 26.3(b) require him or her to have the following types of access or perform the following activities shall be subject to an FFD program that meets all of the requirements of this part, except subparts I and K of this part:

(1) All persons who are granted unescorted access to Category IA material;

(2) All persons who create or have access to procedures or records for safeguarding SSNM;

(3) All persons who measure Category IA material;

(4) All persons who transport or escort Category IA material; and

(5) All persons who guard Category IA material.

(e) When construction activities begin, any individual whose duties for the licensees and other entities in § 26.3(c) require him or her to perform the following activities at the location where the nuclear power plant will be constructed and operated shall be subject to an FFD

program that meets all of the requirements of this part, except subparts I and K of this part:

(1) Serves as a security officer under NRC requirements;

(2) Performs quality assurance activities, as specified in Appendix B to part 50;

(3) Is designated under § 26.406 by a licensee or other entity to monitor the fitness of the individuals specified in paragraph (f) of this section; or

(4) Has responsibility for determining that inspections, tests, and analyses, or parts thereof, required under part 52 of this chapter have been successfully completed.

(f) Any individual who is constructing safety- or security-related structures, systems, and components (SSCs) shall be subject to an FFD program that meets the requirements of subpart K of this part, unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of this part, except subparts I and K of this part.

(g) All FFD program personnel who are involved in the day-to-day operations of the program, as defined by the procedures of the licensees and other entities in § 26.3(a), (b), and, as applicable, (c) and (d), and whose duties require them to have the following types of access or perform the following activities shall be subject to an FFD program that meets all of the requirements of this part, except subparts I and K of this part, and, at the licensee's or other entity's discretion, subpart C of this part:

(1) All persons who 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) All persons who make determinations of fitness;

(3) All persons who make authorization decisions;

(4) All persons involved in selecting or notifying individuals for testing; and

(5) All persons involved in the collection or on-site testing of specimens.

(h) Individuals who have applied for authorization to have the types of access or perform the activities described in paragraphs (a) through (d) of this section shall be subject to

§§ 26.31(c)(1), 26.35(b), 26.37, 26.39, and the applicable requirements of subparts C, and E through H of this part.

(i) The following individuals are not subject to an FFD program under this part:

(1) Individuals who are not employed by a licensee or other entity in this part, who do not routinely provide FFD program services to a licensee or other entity in this part, and whose normal workplace is not at the licensee's or other entity's facility, but who may be called on 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;

(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; and

(4) The FFD program personnel of a program that is regulated by another Federal agency or State on which a licensee or other entity relies to meet the requirements of this part, as permitted under §§ 26.4(j), 26.31(b)(2), and 26.405(e), if the FFD program personnel are not employed by the licensee or other entity and their normal workplace is not at the licensee's or other entity's facility.

(j) 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 an 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 EBT 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 the Department of Health and Human Services (HHS);

(4) Training is provided to address the knowledge and abilities (KAs) listed in § 26.29(a)(1) through (a)(10); and

(5) Provisions are made to ensure that the testing agency or organization notifies the licensee or other entity granting authorization of any FFD policy violation.

§ 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 has been altered, as evidenced by test results showing either a substance that is not a normal constituent of urine or showing an abnormal concentration of an endogenous substance.

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 any licensee testing facility or HHS-certified

laboratory that continuously processes 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.

Authorization means that a licensee or other entity in § 26.3 has determined that an individual has met the requirements of this part to be granted or maintain the types of access or perform the duties specified in § 26.4(a) through (e), and, at the licensee's or other entity's discretion, § 26.4(f) or (g).

Best effort means documented actions that a licensee or other entity who is subject to subpart C of this part takes to obtain suitable inquiry and employment information in order to determine whether an individual may be granted authorization, 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 on 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 centimeters 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 subpart E, 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 (NRC) 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 and/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 confirmatory substituted or adulterated validity test result from the HHS-certified laboratory for that donor. For alcohol, a confirmed test result is based on a positive confirmatory alcohol test result from an evidential breath testing device (EBT) without MRO review of the test result.

Constructing or construction activities mean, for the purposes of this part, the tasks involved in building a nuclear power plant that are performed at the location where the nuclear power plant will be constructed and operated. These tasks include fabricating, erecting, integrating, and testing the nuclear power plant SSCs that are required by the Commission's rules and regulations to be described in the site safety analysis report, preliminary or final safety analysis report, or physical security or safeguards contingency plans, and the installation of their foundations, including the placement of concrete.

Contractor/vendor (C/V) means any company, or any individual not employed by a licensee or other entity specified in § 26.3(a) through (c), who is providing work or services to a licensee or other entity covered in § 26.3(a) through (c), either by contract, purchase order, oral 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 or decision criteria established for designating and reporting a test result as positive, of questionable validity (referring to validity screening or initial validity test results from a licensee testing facility), or adulterated, substituted, dilute, or invalid

(referring to initial or confirmatory test results from an HHS-certified laboratory).

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 in the execution of the work activity, and either makes technical decisions for that activity without subsequent technical review, or is ultimately responsible for the correct performance of that work activity.

Donor means the individual from whom a specimen is collected.

Eight (8)-hour shift schedule means a schedule that averages not more than 9 hours per workday over the entire shift cycle.

Employment action means a change in job responsibilities or removal from a job, or the employer-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 SSNM 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 (the HHS Guidelines), 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 to 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.

Increased threat condition means an increase in the protective measure level, relative to the lowest protective measure level applicable to the site during the previous 60 days, 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, dilute, substituted, or invalid, 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 and specimen validity testing facility that is operated by a licensee or other entity who is subject to this part to perform 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 drug and validity 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.

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(a) through (c), 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.

Positive result means, for drug testing, the result reported by a licensee testing facility or

HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentration. A result reported by an HHS-certified laboratory that a specimen contains a drug or drug metabolite below the cutoff concentration is also a positive result when the laboratory has conducted the special analysis permitted in § 26.163(a)(2). For alcohol testing, a positive result means the result reported by a collection site when the BAC indicated by testing a specimen exceeds the cutoff concentrations established in this part.

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 §§ 26.35(c)(2), 26.61(d), 26.63(d), 26.65(g), 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."

Questionable validity means the results of validity screening or initial validity tests at a

licensee testing facility indicating that a urine specimen may be adulterated, substituted, dilute, or invalid.

Reviewing official means an employee of a licensee or other entity specified in § 26.3(a), (b), and, if applicable, (c), who is designated by the licensee or other entity to be 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.

Safety-related SSCs mean, for the purposes of this part, those structures, systems, and components that are relied on to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in 10 CFR 50.34(a)(1).

Security-related SSCs mean, for the purposes of this part, those structures, systems, and components that the licensee will rely on to implement the licensee's physical security and safeguards contingency plans that either are required under part 73 of this chapter if the licensee is a construction permit applicant or holder as described in § 26.3(c), or are included in the licensee's application if the licensee is a combined license applicant or holder as described in 26.3(c).

Shift cycle means a series of consecutive work shifts and days off that is planned by the licensee or other entity to repeat regularly, thereby constituting a continuous shift schedule.

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 uranium-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, and test result reporting), and adulterating, substituting, or otherwise causing a specimen to provide an inaccurate test result.

Ten (10)-hour shift schedule means a schedule that averages more than 9 hours, but not more than 11 hours, per workday over the entire shift cycle.

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.

Twelve (12)-hour shift schedule means a schedule that averages more than 11 hours, but not more than 12 hours, per workday over the entire shift cycle.

Unit outage means, for the purposes of this part, that the reactor unit is disconnected from the electrical grid.

Validity screening test means a test to determine the need for initial validity testing of a urine specimen, using a non-instrumented test in which the endpoint result is obtained by visual evaluation (read by the human eye), or a test that is instrumented to the extent that results are machine-read.

Validity screening test lot means a group of validity screening tests that were made from the same starting material.

§ 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 on 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, 26.53, 26.55, 26.57, 26.59, 26.61, 26.63, 26.65, 26.67, 26.69, 26.75, 26.77, 26.85, 26.87, 26.89, 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, 26.168, 26.169, 26.183, 26.185, 26.187, 26.189, 26.203, 26.205, 26.207, 26.211, 26.401, 26.403, 26.405, 26.406, 26.411, 26.413, 26.415, 26.417, 26,711, 26.713, 26.715, 26.717, 26.719, and 26.821.

§ 26.9 Specific exemptions.

Upon application of any interested person or on 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 to 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, email, 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 email to 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.

The licensees and other entities specified in § 26.3(a) through (c) shall establish,

implement, and maintain FFD programs that, at a minimum, comprise the program elements contained in this subpart. The individuals specified in § 26.4(a) through (e) and (g), and, at the licensee's or other entity's discretion, § 26.4(f), and, if necessary, § 26.4(j) shall be subject to these FFD programs. Licensees and other entities may rely on 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 reasonable assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse;

(b) Provide reasonable assurance that individuals 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 duties that require them to be subject to the FFD program;

(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 [Reserved.]

§ 26.27 Written policy and procedures.

(a) *General*. Each licensee and other entity 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 actions that constitute a refusal to provide a specimen for testing, the consequences of a refusal to test, 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 duties that require an individual to be subject to this subpart;

(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 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 other rights (including due process) 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 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, or consumed any alcohol 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. 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 for an unscheduled working tour, including an unscheduled working tour to respond to an emergency, the procedure must—

(A) Require a determination of fitness by breath alcohol analysis or other means;

(B) Permit the licensee or other entity to assign the individual to duties that require him or her to be subject to this subpart, if the results of the determination of fitness indicate that the individual is fit to safely and competently perform his or her duties;

(C) Prohibit the licensee or other entity from assigning the individual to duties that require him or her to be subject to this subpart, if the individual is not required to respond to an emergency and the results of the determination of fitness indicate that the individual may be impaired;

(D) State that 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. However, if the determination of fitness indicates that an individual who has been called in for an unscheduled working tour to respond to an emergency may be impaired, the procedure must require the establishment of controls and conditions under which the individual who has been called in can perform work, if necessary; and

(E) State that no sanctions may be imposed on an individual who is called in to perform any unscheduled working tour for having 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 safely 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 the individuals who are subject to this subpart have the following 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 subpart 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 subpart 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. Indications of the need for more frequent training include, but are not limited to, an individual's failure to properly implement FFD program procedures and the frequency, nature, or severity of problems discovered through audits or the administration of the program. 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 training program that meets the requirements of

this section 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 subpart.

(b) *Assuring the honesty and integrity of FFD program personnel*. (1) Licensees and other entities who are subject to this subpart shall carefully select and monitor FFD program personnel, as defined in § 26.4(g), based on the highest standards of 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 that are conducted 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 a donor 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 under 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 may rely on 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 § 26.4(g).

(c) *Conditions for testing*. Licensees and other entities shall administer drug and alcohol

tests to the individuals who are subject to this subpart under the following conditions:

(1) Pre-access. In order to grant initial, updated, or reinstated authorization to an individual, as specified in subpart C of this part;

(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 subpart, 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 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 1904.7, "General Recording Criteria," 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 under paragraph (d)(1)(i) of this section to the panel of substances for testing, but only if the additional drugs are listed in Schedules I through 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 who has no relationships with manufacturers of the assays or instruments to be used or the HHS-certified laboratory that will conduct the testing for the licensee or other entity, which could be construed as a potential conflict of

interest. 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 holds, has held, or is eligible to hold, the position of Responsible Person at an HHS-certified laboratory, as specified in § 26.155(a). All new assays and cutoff levels must be properly validated consistent 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 through 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 under 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, except if the specimen is dilute and the licensee or other entity has requested the HHS-certified laboratory to evaluate the specimen under §§ 26.163(a)(2) or 26.185(g)(3).

(iii) The licensee or other entity shall document the additional drug(s) for which testing will be performed in written policies and procedures in which the substances for which testing will be performed are described.

(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. In the latter instance, the portions of each day and the days of the week must vary in a manner that cannot be predicted by donors; 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;

(v) Require that individuals who are off site when selected for testing, or who are on site and are 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;

(vi) Provide that an individual completing a test is immediately eligible for another unannounced test; and

(vii) 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 and validity, except validity screening and initial drug and validity 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 initial drug testing by the laboratory. Specimens that yield positive initial drug test results or are determined by initial validity testing to be of questionable validity 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, initial validity, and initial 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 at either the licensee testing facility or HHS-certified laboratory, and in § 26.163(b)(1) for confirmatory drug testing at the HHS-certified laboratory. At their discretion, licensees and other entities may implement programs with lower cutoff levels in testing for drugs and drug metabolites.

(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 subpart. 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), 26.163(a)(2), and 26.165(c)(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 EBT 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 shall ensure that the individuals who are subject to this subpart are subject to behavioral observation. Behavioral observation must be performed by individuals who are trained under § 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 public health and safety or the common defense and security. Individuals who are subject to this subpart shall report any FFD concerns about other individuals 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 individuals who have problems that could adversely affect the individuals' 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, including those whose work location is a licensee's or other entity's facility, or to individuals who have applied for, but have not yet been granted, authorization under subpart C of this part.

(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 § 26.719(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 subpart who collects personal information about an individual for the purpose of complying with this part, shall establish, use, and maintain a system of files and procedures that protects the individual's 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 to perform their assigned duties under the FFD program, including determinations of fitness, FFD program audits, or some 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 subpart 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 FFD program, including but not limited to, the collection site, HHS-certified laboratory, substance abuse expert (SAE), or MRO, possessing such records shall promptly provide copies of all FFD records pertaining to the individual, including, but not limited to, records pertaining to a determination that the individual has violated the FFD policy, drug and alcohol test results, MRO reviews, determinations of fitness, 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 on request.

(e) A licensee's or other entity's contracts with HHS-certified laboratories and C/Vs providing specimen collection services, and licensee testing facility procedures, must require test records to 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 subpart 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 individual who conducts the review is not associated with the administration of the FFD program [see the description of FFD program personnel in § 26.4(g)]. 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) When a C/V is administering an FFD program on which licensees and other entities rely, and the C/V determines that its employee, subcontractor, or applicant has violated its FFD policy, the C/V shall ensure that the review procedure required in this section is provided to the individual. Licensees and other entities who rely on a C/V's FFD program need not provide the review procedure required in this section to a C/V's employee, subcontractor, 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 subpart 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, any FFD program services that are provided to the C/V by a subcontractor, and the programs of the HHS-certified laboratories on 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 subpart 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 FFD program performance, including, but not limited to, the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, and previous audit findings.

(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 subpart 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 § 26.4(i)(1).

(d) *Contracts*. (1) The contracts of 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 subpart, 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 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 subpart, 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 on 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 subpart. 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 subpart within the past 12 months.

Subpart C—Granting and Maintaining Authorization

§ 26.51 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a) and (b) for the categories of individuals in § 26.4(a) through (d), and, at the licensee's or other entity's discretion, in § 26.4(g) and, if necessary, § 26.4(j). The requirements in this subpart also apply to the licensees and other entities specified in § 26.3(c) for the categories of individuals in § 26.4(e). At the discretion of a licensee or other entity in § 26.3(c), the requirements of this subpart also may be applied to the categories of individuals identified in § 26.4(f). In addition, the requirements in this subpart apply to the entities in § 26.3(d) to the extent that a licensee or other entity relies on the C/V to meet the requirements of this subpart. Certain requirements in this subpart also apply to the individuals specified in § 26.4(h).

§ 26.53 General provisions.

(a) In order to grant authorization to an individual, a licensee or other entity shall ensure that the requirements in this subpart have been met for either 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 on 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 on 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 26.203(c) before granting authorization to the individual.

(d) Licensees and other entities who are seeking to grant authorization to an individual who is maintaining authorization under another FFD program that is implemented by a licensee or entity who is subject to this subpart may rely on the transferring FFD program to satisfy the requirements of this subpart. 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 applicable requirements of this part. The receiving FFD program shall ensure that the program elements to which the individual is subject under the transferring FFD program remain current.

(e) Licensees and other entities in § 26.3(a) through (c) may also rely on a C/V's FFD program or program elements when granting or maintaining the authorization of an individual who is or has been subject to the C/V's FFD program, if the C/V's program or program elements meet the applicable requirements of this part.

(1) A C/V's FFD program may grant and maintain an individual's authorization, as defined in § 26.5, under the C/V's FFD program. However, only a licensee or other entity in § 26.3(a) through (c) may grant or maintain an individual's authorization to have the types of access or perform the duties specified in § 26.4(a) through (e) and (g), and, at the licensee's or other entity's discretion, § 26.4(f).

(2) If a C/V's FFD program denies or unfavorably terminates an individual's authorization, and the individual is performing any duties for a licensee or other entity that are specified in § 26.4(a) through (e) and (g), or, at the licensee's or other entity's discretion, § 26.4(f), then the C/V shall inform the affected licensee or other entity of the denial or unfavorable termination. The licensee or other entity shall deny or unfavorably terminate the individual's authorization to perform those duties on the day that the licensee or other entity

receives the information from the C/V, or implement the applicable process in § 26.69 to maintain the individual's authorization.

(3) If an individual is maintaining authorization under a C/V's FFD program, a licensee or other entity in § 26.3(a) through (c) may grant authorization to the individual to have the types of access and perform the duties specified in § 26.4(a) through (e) and (g), and, at the licensee's or other entity's discretion, § 26.3(f), and maintain his or her authorization, if the individual continues to be subject to either the receiving FFD program or a combination of elements from the receiving FFD program and the C/V's program that collectively satisfy the applicable requirements of this part. The receiving licensee's or other entity's FFD program shall ensure that the program elements to which the individual is subject under the C/V's FFD program remain current.

(f) Licensees and other entities who are seeking to grant authorization to an individual who has been subject to an FFD program under subpart K may not rely on that program or its program elements to meet the requirements of this subpart, except if the program or program element(s) of the FFD program for construction satisfy the applicable requirements of this part.

(g) The licensees and C/Vs specified in § 26.4(a) and, as applicable, (d), shall identify any violation of any requirement of this part to any licensee who has relied on or intends to rely on the FFD program element that is determined to be in violation of this part.

(h) The licensees and other entities specified in § 26.4(a) and, as applicable, (d), may not initiate any actions under this subpart without the knowledge and written consent of the subject individual. The individual may withdraw his or her consent at any time. If an individual withdraws his or her consent, the licensee or other entity may not initiate any elements of the authorization process specified in this subpart that were not in progress at the time the individual withdrew his or her consent, but shall complete and document any elements that are in progress at the time consent is withdrawn. The licensee or other entity shall record the

individual's application for authorization; his or her withdrawal of consent; the reason given by the individual for the withdrawal, if any; and any pertinent information gathered from the elements that were completed (e.g., the results of pre-access drug tests, information obtained from the suitable inquiry). The licensee or other entity to whom the individual has applied for authorization shall inform the individual that—

(1) Withdrawal of his or her consent will withdraw the individual's current application for authorization under the licensee's or other entity's FFD program; and

(2) Other licensees and entities will have access to information documenting the withdrawal as a result of the information sharing that is required under this part.

(i) The licensees and other entities specified in § 26.4(a) and, as applicable, (d), shall inform, in writing, any individual who is applying for authorization that the following actions related to providing and sharing the personal information required under this subpart are sufficient cause for denial or unfavorable termination of authorization:

(1) Refusal to provide written consent for the suitable inquiry;

(2) Refusal to provide or the falsification of any personal information required under this part, including, but not limited to, the failure to report any previous denial or unfavorable termination of authorization;

(3) Refusal to provide written consent for the sharing of personal information with other licensees or C/Vs required under this part; and

(4) Failure to report any legal actions, as defined in § 26.5.

§ 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 ensure

that—

(1) A self-disclosure has been obtained and reviewed under the applicable requirements of § 26.61;

(2) A suitable inquiry has been completed under the applicable requirements of § 26.63;

(3) The individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65; and

(4) The individual is subject to random drug and alcohol testing under 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 under § 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 ensure that—

(1) A self-disclosure has been obtained and reviewed under the applicable requirements of § 26.61;

(2) A suitable inquiry has been completed under the applicable requirements of § 26.63;

(3) The individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65; and

(4) The individual is subject to random drug and alcohol testing under 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 under § 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 ensure that—

(1) A self-disclosure has been obtained and reviewed under the applicable requirements of § 26.61;

(2) A suitable inquiry has been completed under 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) The individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65; and

(4) The individual is subject to random drug and alcohol testing under 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, except if the individual's authorization was subsequently denied or terminated unfavorably by the licensee or other entity.

(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 ensure that—

(1) A self-disclosure has been obtained and reviewed under the applicable requirements of § 26.61;

(2) The individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65, if the individual's authorization was interrupted for more than 5 days; and

(3) The individual is subject to random drug and alcohol testing under 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 under § 26.69.

§ 26.61 Self-disclosure and employment history.

(a) Before granting authorization, the licensee or other entity shall ensure that a written self-disclosure and employment history has been obtained 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 program that includes arrest reporting, which 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 §§ 26.35(c)(2), 26.61(d), 26.63(d), 26.65(g), 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 employer by whom the individual claims to have been employed on the day before he or she completes the employment history, 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.

§ 26.63 Suitable inquiry.

(a) In order to grant authorization, licensees and other entities shall ensure that a suitable inquiry has been conducted, 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 program that includes arrest reporting, which meets the requirements of this part, throughout the period of interruption.

(b) To meet the suitable inquiry requirement, licensees and other entities may rely on the information that other licensees and entities who are subject to this subpart have gathered for previous periods of authorization. Licensees and other entities may also rely on those licensees' and entities' determinations of fitness that were conducted under § 26.189, as well as their reviews and resolutions of potentially disqualifying FFD information, for previous periods of authorization.

(c) The licensee or other entity shall ensure that the suitable inquiry has been conducted, on a best effort basis, by questioning former employers, and the employer by whom the individual claims to have been employed on the day before he or she completes the employment history, if an employment history is required under § 26.61.

(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, but shall evaluate and document the response if it is received.

(d) When any licensee or other entity in § 26.3(a) through (d) is legitimately seeking the information required for an authorization decision under this subpart and has obtained a signed release from the subject individual authorizing the disclosure of information, any licensee or

other entity who is subject to this part 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 on which the denial or unfavorable termination of authorization was based, including, but not limited to, drug or alcohol test results, treatment and followup testing requirements or other results from a determination of fitness, and any other information that is relevant to an authorization decision.

(e) In conducting a suitable inquiry, a 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, under §§ 26.711 and 26.713(a), (b), and (c), as applicable.

(f) For individuals about whom no potentially disqualifying FFD information is known (or about whom potentially disqualifying FFD information is known, but it has been resolved by a licensee or other entity who is subject to this subpart) at the time at which the suitable inquiry is initiated, the licensee or other entity shall ensure that a suitable inquiry has been conducted 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 on which the individual applies for authorization, the licensee or other entity shall ensure that the suitable inquiry has been conducted with every employer, regardless of the length of employment. For the remaining 2-year period, the licensee or other entity shall ensure that the suitable inquiry has been conducted 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 on which the individual applies for authorization, the licensee or other entity shall ensure that the suitable inquiry has been conducted with every employer, regardless of the length of employment. For the remaining period since authorization was terminated, the licensee or other entity shall ensure that the suitable inquiry has been conducted 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 ensure that the suitable inquiry has been conducted 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 under the requirements of this subpart.

(b) *Accepting tests conducted within the past 30 days*. If an individual has negative results from drug and alcohol tests that were conducted under 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 on which the licensee or other entity grants authorization to the individual, the licensee or other entity may rely on 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 held authorization 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, which must be performed within the 30-day period preceding the day the licensee or other entity grants authorization to the individual, are negative. The licensee or other entity need not conduct pre-access testing if—

(1) The individual previously held authorization under this part and has been subject to a drug and alcohol testing program that includes random testing and a behavioral observation program that includes arrest reporting, which both meet the requirements of this part, from the date the individual's last authorization was terminated through the date the individual is granted authorization; or

(2) The licensee or other entity relies on negative results from drug and alcohol tests that were conducted under the requirements of this part at any time before the individual applied for authorization, and the individual has remained subject to a drug and alcohol testing program that includes random testing and a behavioral observation program that includes arrest reporting, which both meet the requirements of this part, beginning on the date the drug and alcohol testing was conducted through the date the individual is granted authorization and thereafter.

(d) *Authorization reinstatement after an interruption of more than 30 days*. (1) 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 within the 30-day period preceding the day the licensee reinstates the

individual's 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 to a drug and alcohol testing program that includes random testing and a behavioral observation program that includes arrest reporting, which both meet the requirements of this part, beginning on the date the individual's last authorization was terminated through the date the individual is granted authorization; or

(ii) The licensee or other entity relies on negative results from drug and alcohol tests that were conducted under the requirements of this part at any time before the individual applied for authorization, and the individual remains subject to a drug and alcohol testing program that includes random testing and a behavioral observation program that includes arrest reporting, which both meet the requirements of this part, beginning on the date the drug and alcohol testing was conducted through the date 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. In addition, the licensee or other entity need not conduct pre-access testing if the individual has been subject to a drug and alcohol testing program that includes random testing and a behavioral observation program that includes arrest reporting, which both meet the requirements of this part, from the date the individual's last authorization was terminated through the date the individual is granted authorization.

(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)(1) 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)(vii) calculated for a 30-day period;

(ii) If the individual is not selected for pre-access testing under paragraph (e)(2)(i) of this section, 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.

(f) *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, except if the individual's authorization was subsequently denied or terminated unfavorably by a licensee or entity. Immediately on 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 donor's personnel record and other records.

(g) *Sanctions*. If an individual has confirmed positive, adulterated, or substituted 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, under § 26.75(e)(1) or (f); or

(3) Grant authorization to the individual under § 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 under § 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 on drug and alcohol tests that were conducted before the individual applied for authorization to meet the applicable requirements for pre-access testing. If the licensee or other entity relies on 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, if the individual has met all other applicable requirements for authorization.

(c) If an individual has confirmed positive, adulterated, or substituted 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 under § 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 subpart shall take 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 any FFD program under this part, 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 under this section.

(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). To grant, and subsequently maintain, the individual's authorization, the licensee or other entity shall—

(1) Obtain and review a self-disclosure and employment history from the individual that addresses the shorter period of either the past 5 years or since the individual's last period of

authorization was terminated, 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 employment history obtained under paragraph (b)(1) of this section, 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 has conducted a determination of fitness and concluded 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 and followup testing plans have been developed by an 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 an 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 3 calendar years after the date the individual is 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 followup testing program may be extended up to 5 calendar 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. If potentially disqualifying FFD information is obtained about an individual by any means,

including, but not limited to, the individual's self-disclosure, the suitable inquiry, the administration of any FFD program under this part, 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, before granting authorization to the individual, the licensee or other entity shall—

(1) Obtain and review a self-disclosure and employment history that addresses 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;

(2) Complete a suitable inquiry with every employer by whom the individual claims to have been employed during the period addressed in the employment history required under paragraph (c)(1) of this section. If the individual held authorization within the past 5 years, 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 a urine specimen 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 complies with and successfully completes the treatment plans.

(e) *Accepting followup testing and treatment plans from another FFD program*. Licensees and other entities may rely on followup testing, treatment plans, and determinations of fitness that meet the requirements of § 26.189 and were conducted under the FFD program of another licensee or entity who is subject to this subpart.

(1) If an individual leaves the FFD program in which a treatment and/or followup testing plan was required under paragraphs (b), (c), or (d) of this section, the licensee or other entity who imposed the treatment and/or followup testing plan shall ensure that information documenting the treatment and/or followup testing plan is identified to any subsequent licensee or other entity who seeks to grant authorization to the individual. If the individual 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 followup testing requirements are met and that the individual complies with any treatment plan, with accountability assumed by the granting licensee or other entity. If it is impractical for the individual to comply with a treatment plan that was developed under another FFD program because of circumstances that are outside of the individual's or licensee's or other entity's control (e.g., geographical distance, closure of a treatment facility), then the granting FFD program shall ensure that an SAE develops a comparable treatment plan, with accountability for monitoring the individual's compliance with the plan 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 on the previous determination of fitness and no further review or followup is required.

(f) *Sanctions*. If an individual has confirmed positive, adulterated, or substituted 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 and procedures, as described in § 26.27, 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 meets the

requirements of § 26.31, including random testing;

(3) The individual remains subject to a behavioral observation program that meets the requirements of § 26.33; and

(4) The individual successfully completes required FFD training on 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 section 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

§ 26.73 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a) and (b) for the categories of individuals specified in § 26.4(a) through (d) and (g). The requirements in this subpart also apply to the licensees and other entities specified in § 26.3(c) for the categories of individuals in § 26.4(e). At the discretion of a licensee or other entity in § 26.3(c), the requirements of this subpart also may be applied to the categories of individuals identified in § 26.4(f). In addition, the requirements in this subpart apply to the entities in § 26.3(d) to the extent that a licensee or other entity relies on the C/V to meet the requirements of this subpart. The regulations in this subpart also apply to the individuals specified in § 26.4(h) and (j), as appropriate.

§ 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 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 § 26.31(c) 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 duties that require the individual to be subject to this subpart shall immediately have his or her authorization unfavorably terminated and denied 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 section 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 from the date of the unfavorable termination.

(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)(2), 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 may not terminate an individual's authorization and may not subject the individual to other administrative action based solely on a positive test result from any initial drug test, other than positive initial test results for marijuana or cocaine metabolites from a specimen that is reported 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. The licensee or other entity may not terminate an individual's authorization or subject an individual to any other administrative action under this section based on the results of validity screening or initial validity testing performed at a licensee testing facility indicating that a specimen is of questionable validity.

(i) With respect to positive initial drug test results from a licensee testing facility for marijuana and cocaine metabolites from a valid specimen, licensee testing facility personnel may inform licensee or other entity management of the positive 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, 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 § 26.717 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 on 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 §§ 26.713 and 26.715 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 who are subject to this subpart must take when an individual who is subject to this subpart 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), 26.207, and 26.209, the licensee or other entity shall

take immediate action to prevent the individual from performing the duties that require him or her to be subject to this subpart.

(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 testing. The results must be negative before the individual returns to performing the duties that require the individual to be subject to this subpart. 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 of this part 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 under § 26.211. If the results of the fatigue assessment confirm that the observed behavior or physical condition is the result solely of fatigue, the licensee or C/V need not perform drug and alcohol tests or implement the determination of fitness process otherwise required by § 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 of this part), the licensee or other entity may permit the individual to return to performing his or her 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 oral 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 and applicability.

This subpart contains requirements for collecting specimens for drug testing and conducting alcohol tests by or on behalf of the licensees and other entities in § 26.3(a) through (d) for the categories of individuals specified in § 26.4(a) through (d) and (g). At the discretion of a licensee or other entity in § 26.4(c), specimen collections and alcohol tests must be conducted either under this subpart for the individuals specified in § 26.4(e) and (f) or the licensee or other entity may rely on specimen collections and alcohol tests conducted under the requirements of 49 CFR part 40 for the individuals specified in § 26.4(e) and (f). The requirements of this subpart do not apply to specimen collections and alcohol tests that are conducted under the requirements of 49 CFR part 40, as permitted in this paragraph and under §§ 26.4(j) and 26.31(b)(2).

§ 26.83 Specimens to be collected.

Except as permitted under § 26.31(d)(5), licensees and other entities who are subject to this subpart 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 and 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 and 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 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, only if all of the following conditions are met:

(1) A collector who meets the requirements of paragraphs (a) or (b) of this section cannot reasonably be made available at the time the collection must occur;

(2) The individual is not employed by the licensee's or other entity's FFD program and his or her normal workplace is not at the licensee's or other entity's facility;

(3) The individual does not routinely provide FFD program services to the licensee or other entity;

(4) The individual is licensed or otherwise approved to practice in the jurisdiction in which the collection occurs; and

(5) The individual is provided with detailed, clearly-illustrated, written instructions for collecting specimens under this subpart and follows 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

positive drug or alcohol test results or adulterated or substituted test results from specimens collected by or under contract to the licensee or other entity.

(e) *Files*. Collection site 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 to establish employee competency for the position he or she holds, including, but not limited to, certification that collectors are proficient in administering alcohol tests consistent with the most recent manufacturer's instructions for the instruments and devices used; and appropriate data to support determinations of honesty and integrity conducted under § 26.31(b).

§ 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; 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 section 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;

(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, as required by § 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. When so informed, FFD program management shall contact the individual's supervisor to verify in-person the individual's identity, or, if the supervisor is not available, take other steps to establish the individual's identity and determine whether the lack of identification was an attempt to subvert the testing process. The donor may not leave the collection site except under supervision until his or her identity has been established.

(3) 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.

(4) 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 refuses to cooperate in the specimen collection process (including, but not limited to, behaving in a confrontational manner that disrupts the testing process; admitting to the collector that he or she adulterated, diluted, or adulterated the specimen; is found to have a device, such as a prosthetic appliance, the purpose of which is to interfere with providing an actual urine specimen; or leaving the collection site before all of the collection procedures are completed), it will be considered a refusal to test, and sanctions for subverting the testing process will be imposed under § 26.75(b). If the donor 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 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 subpart.

(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 subpart:

(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. The EBT may not be used again for alcohol testing under this subpart until it is repaired and passes an external calibration check.

(4) In order to ensure that confirmed positive alcohol test results are derived from an

EBT that is calibrated, the licensee or other entity shall implement one of the following procedures:

(i) If an EBT fails any external check of calibration, cancel every confirmed positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed the last external calibration check; or

(ii) After every confirmed positive test result obtained from using an EBT, conduct an external check of calibration of the EBT in the presence of the donor. If the EBT fails the external calibration check, cancel the donor's test result and conduct another initial and confirmatory test on a different EBT as soon as practicable.

(5) Inspection, maintenance, and calibration of the EBT must be performed by its manufacturer or a maintenance representative or other individual who is 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 § 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 as required by 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 on 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 when 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 as required by 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 on 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 the individual to be subject to this subpart 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 or substitute 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 subpart 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 under § 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 subpart, 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 40 ounces 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 quantity 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 quantity 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 under 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 on 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 acceptability 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. If the temperature of a urine specimen is outside the range of 90 ºF to 100 ºF (32 ºC to 38 ºC), that is a reason to believe the donor may have altered or substituted the specimen.

(b) Immediately after the donor provides a urine specimen, including specimens of less than 30 mL but equal to or 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.

(c) If there is reason to believe that the donor may have attempted to dilute, substitute, or adulterate the specimen based on 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 under direct observation. In addition, the collector shall inform the donor that he or she may volunteer to submit a second specimen under direct observation to counter the reason to believe the donor may have altered or substituted the specimen.

(d) Any specimen of 15 mL or more that the collector suspects has been diluted, substituted, or adulterated, and any specimen of 15 mL or more that has been collected under direct observation under paragraph (c) of this section, must be sent directly to the HHS-certified laboratory for initial and, if required, confirmatory testing, and may not be subject to initial testing at a licensee testing facility.

(e) As much of the suspect specimen as possible must be preserved.

(f) 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 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 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. The collector shall pour 30 mL of urine into Bottle A and a minimum of 15 mL of urine into Bottle B. If the quantity of urine available for Bottle B is less than 15 mL, the collector shall pour the remaining urine into Bottle B and forward the specimens in Bottles A and B to the HHS-certified laboratory for drug and validity 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 this 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 subpart 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;

(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 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, the donor's refusal constitutes an act to subvert the testing process.

(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, including, but not limited to, certification that personnel are proficient in conducting testing in accordance with manufacturer's most recent instructions for the instruments and devices used and tests for color blindness; and appropriate data to support determinations of honesty and integrity required by 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, the licensee testing facility shall develop, implement, and maintain written standard operating procedures for each test. 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 test setup and normal operation, including the following:

(1) A schedule for checking critical operating characteristics for all instruments and validity screening tests;

(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 instrumented and non-instrumented 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 must be secure at all times. Each licensee or other entity shall have sufficient security measures in place to control access to the licensee testing facility 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 the 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. When resolving any discrepancies, licensee testing facility personnel shall obtain a memorandum for the record from the specimen collector involved in the discrepancy to document correction of the discrepancy. This memorandum must accompany the specimen(s) and custody-and-control forms to the HHS-certified laboratory if the specimen(s) must be transferred.

(1) 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 a report, licensee or other entity management personnel shall initiate an investigation to determine whether tampering has occurred.

(i) If the investigation determines that tampering has occurred, licensee or other entity management shall ensure that corrective actions are taken.

(ii) 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 the 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, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, the licensee testing facility shall forward the intact specimen for testing

to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen:

(i) The custody-and-control form does not contain information to identify the specimen collector and the collection site cannot provide conclusive evidence of the collector's identity;

(ii) The identification numbers on the specimen bottle seal(s) do not match the identification numbers on the custody-and-control form;

(iii) A specimen bottle seal is broken or shows evidence of tampering and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist;

(iv) The specimen appears to have leaked out of its sealed bottle and there is less than 15 mL remaining, and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist; or

(v) As required under § 26.165(f)(2).

(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 positive or of questionable validity 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 or initial validity testing indicate that the specimen is of questionable validity, or initial drug test results are positive, 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 positive specimens or specimens of questionable validity 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, under § 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 questionable 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) The pH of the specimen is either less than 4.5 or equal to or greater than 9, using either a colorimetric pH test with a dynamic range of 2 to 12 or pH meter that is capable of measuring pH to one decimal place (for initial validity tests), or colorimetric pH tests, dipsticks, and pH paper (for pH validity screening tests) that have a narrow dynamic

range;

(3) Nitrite or other oxidant concentration is equal to or greater than 200 micrograms (mcg) per mL or equal to or greater than 200 mcg/mL nitrite-equivalents using either a nitrite colorimetric test or a general oxidant colorimetric test;

(4) The possible presence of an oxidizing adulterant (e.g., chromium (VI), pyridine (pyridinium chlorochromate)) is determined 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) The possible presence of halogen (e.g., bleach, iodine, fluoride) is determined using 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), a halogen colorimetric test (halogen concentration equal to or greater than the limit of detection (LOD)), or the odor of the specimen;

(6) The possible presence of glutaraldehyde is determined using either an aldehyde test (aldehyde present) or the characteristic immunoassay response is observed on one or more drug immunoassay tests;

(7) The possible presence of a surfactant is determined by using a surfactant colorimetric test with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent or a foam/shake test; or

(8) 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 validity screening or initial test; or

(iii) A 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).

§ 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 [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	2000
Phencyclidine (PCP)	25
Amphetamines	1000

§ 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 Bottle B. If any test results are positive or indicate that

the specimen is of questionable validity, the licensee testing facility shall forward Bottle A to the HHS-certified laboratory for testing and shall retain Bottle B in secure storage, under the requirements of § 26.159(i), or may forward it to the HHS-certified laboratory for storage.

(b) If the MRO confirms any positive, adulterated, or substituted result for a specimen in Bottle A, based on the results of confirmatory testing at an HHS-certified laboratory, and the licensee testing facility has elected to retain Bottle B of the specimen, and the donor requests testing of the specimen in Bottle B, as permitted under § 26.165(b), the MRO shall ensure that Bottle B is forwarded to an HHS-certified laboratory other than the laboratory that tested the specimen in Bottle A, under the procedures specified in § 26.165(b).

(c) If the MRO confirms that the specimen in Bottle A is positive, adulterated, substituted, or invalid 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/-68 ºF or less) for a minimum of 1 year. If a licensee testing facility elects to retain the specimen in Bottle B, rather than forwarding it to the HHS-certified laboratory with Bottle A, the licensee testing facility shall ensure proper storage conditions in the event of a prolonged power failure. 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 and 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 on validity screening tests to determine the need for initial tests of specimen validity either at the licensee testing facility or HHS-certified laboratory. Licensees and other entities shall ensure that the HHS-certified laboratory is capable of conducting confirmatory testing for any adulterant for which the licensee testing facility conducts validity screening tests. Licensee testing facilities shall use only validity screening tests that meet the following criteria:

(i) Either the test, by lot number, has been placed on the Substance Abuse and Mental Health Services Administration (SAMHSA) list of point-of-collection tests that are approved for use in the Federal Workplace Drug Testing Program; or

(ii) Before using the test, the licensee or other entity has ensured that the validity screening test, by lot number, effectively identifies specimens of questionable validity by meeting the following performance testing and quality control requirements:

(A) The creatinine validity screening test must use a 20 mg/dL cutoff concentration;

(B) A pH specimen validity screening test must be able to determine if pH is less than 4.5 and if pH is equal to or greater than 9; and

(C) An oxidant validity screening test must be able to determine if an oxidant concentration is equal to or greater than a 200 mcg/mL nitrite-equivalent cutoff, and/or a chromium screening test must be able to determine concentrations equal to or greater than a 50 mcg/mL chromium(VI)-equivalent cutoff, and/or a halogen screening test must be able to determine the halogen concentration is equal to or greater than the LOD. Licensees and other entities who use validity screening tests for additional adulterants shall establish performance testing requirements to challenge the licensee testing facility and the HHS-certified laboratory

for the additional validity screening test(s);

(D) The manufacturer has conducted validation studies to document the validity screening test's performance characteristics around each applicable cutoff specified in this section, using performance testing samples that have been formulated to challenge the validity screening test around the applicable cutoffs. These validation studies must demonstrate the validity screening test's ability to differentiate valid samples from those of questionable validity and the performance of the validity screening test(s) around the applicable cutoffs specified in this section; and

(E) The licensee testing facility shall submit three consecutive sets of performance testing samples to the manufacturer, using performance testing samples that have been formulated to challenge the validity screening test around the applicable cutoffs specified in this paragraph and whose formulation levels have been confirmed by an HHS-certified laboratory. For example, one set of performance testing samples used to challenge a creatinine validity screening test must include at least six samples formulated at different concentrations ranging from 0 to 20 mg/dL. A set of performance testing samples used to challenge a pH validity screening test must include at least six samples formulated with different pH levels that are equal to or less than 4.5, and six samples formulated with different pH levels that are equal to or greater than 9. And, a set of performance testing samples used to challenge an oxidizing adulterant validity screening test must include at least six samples to challenge each validity screening test used. The performance testing samples for oxidizing adulterants must contain nitrite and other oxidizing adulterant concentrations in a range of less than or equal to a 200 mcg/mL nitrite-equivalent cutoff to a 500 mcg/mL nitrite-equivalent cutoff; chromium samples formulated in a range less than or equal to a 50 mcg/mL chromium(VI)-equivalent cutoff to 100 mcg/mL chromium(VI)-equivalent cutoff; or halogen samples formulated in a concentration at or near the LOD and 25 percent above the LOD. The results of analyzing the three consecutive

sets of performance test samples for each validity screening test (i.e., creatinine, pH, nitrite and general oxidants, chromium, or halogen) must demonstrate that the validity screening test, by lot number, correctly identified at least 90 percent of the total validity performance test challenges on each of three sets of performance testing samples, and, for each individual specimen validity screening test, the test, by lot number, correctly identified at least 90 percent of the validity performance test challenges on each of three sets of performance testing samples; and

(iii) After the licensee testing facility has placed a validity screening test in service, the licensee or other entity shall verify that the test, by lot number, remains on the SAMHSA-approved list. Or, if the SAMHSA-approved list is unavailable, the licensee or other entity shall ensure that the test continues to identify specimens of questionable validity, as demonstrated by documentation from the manufacturer that a set of validity screening tests from each lot in use by the licensee testing facility correctly identified at least 90 percent of the total validity test challenges on a set of performance testing samples, and, for each individual specimen validity screening test, that the test, by lot number, correctly identified at least 90 percent of the validity test challenges. This performance testing must be performed at a nominal annual frequency after the date on which the manufacturer completed the initial validation studies required under paragraph (b)(1)(ii)(D) of this section. The performance testing samples used must be formulated to challenge the validity screening test around the applicable cutoffs of this subpart.

(2) In addition, licensee testing facility personnel who perform the validity screening tests shall conduct quality control testing of validity screening tests as follows:

(i) 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 one quality control sample that is negative for each specific validity test to be performed (e.g., creatinine, pH, nitrites, chromium) during the 8-hour period, and one quality control sample that

is formulated to challenge the validity screening test(s) around the cutoffs specified in this subpart for each specific validity test to be performed during the 8-hour period. The results of these quality control tests must be correct before any donor specimens may be tested.

(ii) After screening every ten donor specimens during the 8-hour period, licensee testing facility personnel shall also challenge each validity screening test with at least one quality control sample that is formulated to challenge the validity screening test(s) around the cutoffs specified in this subpart. If fewer than ten donor specimens were screened during the 8-hour period or the number of donor specimens tested exceeds a multiple of ten but is less than the next multiple of ten (e.g., 24 donor specimens, 48 donor specimens), licensee testing facility personnel shall challenge each validity screening test at the end of the 8-hour period during which the validity screening tests were performed.

(3) The licensee testing facility shall also submit at least one specimen out of every ten donor specimens that test negative using each validity screening test that the licensee testing facility uses to an HHS-certified laboratory as part of the licensee testing facility's quality assurance program.

(4) Licensee testing facilities shall store specimen validity tests as specified by the manufacturer's instructions and may not use such tests after the manufacturer's expiration date.

(c) *Validity screening test results*. If the results of a validity screening test indicate that the specimen is of questionable validity, 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*. Licensees and other entities shall ensure that the HHS-certified laboratory is capable of conducting confirmatory testing for any adulterant for which the licensee testing facility conducts 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 to 20 mg/dL and a control in the range of 21 to 25 mg/dL.

(2) Requirements for performing initial pH tests are as follows:

(i) Colorimetric pH tests that have a dynamic range of 2 to 12 and pH meters and must be capable of measuring pH to one 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 to 2.8;

(D) One control in the range of 3.2 to 4;

(E) One control in the range of 4.5 to 9;

(F) One control in the range of 10 to 10.8; and

(G) One control in the range of 11.2 to 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 to 2.8;

(E) One control in the range of 3.2 to 4;

(F) One control in the range of 10 to 10.8; and

(G) One control in the range of 11.2 to 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 to 2.8; and

(D) One control in the range of 3.2 to 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 to 10.8; and

(D) One control in the range of 11.2 to 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 to 400 mcg/mL, one control in the range of 500 to 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.

(5) Each analytical run performed to conduct initial validity testing shall include at least one quality control sample that appears to be a donor specimen to the laboratory analysts.

(6) The licensee testing facility shall also submit at least one specimen out of every 10 donor specimens that test negative on the initial validity tests performed by the licensee testing facility to an HHS-certified laboratory as part of the licensee testing facility's quality assurance

program.

(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. Licensee testing facilities may not retain any information linking donors to specimens that are pooled for use in the internal quality control program.

(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. For example, a licensee testing facility may use immunoassay technique "A" for all drugs using the licensee's or other entity's cutoff levels, but specimens testing positive for amphetamines may also be tested using immunoassay technique "B" to eliminate any possible positives due to structural analogues; or, a valid analytical result cannot be obtained using immunoassay technique "A" and immunoassay technique "B" is used in an attempt to obtain a valid analytical result.

(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 to the HHS-certified laboratory a minimum of 5 percent (or at least one) of the donor specimens screened as negative from every analytical run.

(6) A minimum of 10 percent of all specimens in each analytical run of specimens to be initially tested for drugs by the licensee testing facility must be quality control samples, which the licensee testing facility shall use for internal quality control purposes. (These samples are not forwarded to the HHS-certified laboratory for further testing, other than for performance testing of the samples.) Licensee testing facilities shall ensure that quality control samples that are positive for each drug and metabolite for which the FFD program conducts testing are included in at least one analytical run each calendar quarter. The quality control samples for each analytical run must include—

(i) Sample(s) certified by an HHS-certified laboratory to contain no drugs or drug metabolites (i.e., negative urine samples);

(ii) At least one positive control with drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff;

(iii) At least one positive control with drug(s) or drug metabolite(s) targeted at 25 percent below 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); and

(v) At least one positive control, certified to be positive by an HHS-certified laboratory, that appears to be a donor specimen to the laboratory analysts.

(7) 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.

(1) Whenever possible, the investigation must determine relevant facts and identify the root cause(s) of the testing or process error.

(2) 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.

(3) If false negative results are obtained in any analytical run from testing the quality control samples specified in paragraphs (b), (d), and (e) of this section at the licensee testing facility, the licensee testing facility shall forward all donor specimens from that analytical run to the HHS-certified laboratory for additional testing and implement corrective actions before resuming testing of donor specimens for the drug(s), drug metabolite(s), adulterant(s), or other specimen characteristics (i.e., creatinine, pH) associated with the quality control sample that yielded the false negative result(s).

(4) If a donor specimen that yielded negative validity or drug test results at the licensee testing facility yields positive, substituted, adulterated, or invalid results after confirmatory testing by the HHS-certified laboratory under paragraphs (b)(3), (d)(6), or (e)(5) of this section, the licensee or other entity shall implement corrective actions before resuming testing of donor specimens for the drug(s), drug metabolite(s), adulterant(s), or other specimen characteristics (i.e., creatinine, pH) associated with the donor specimen that yielded the false negative result(s). In addition to resolving any technical, methodological, or administrative errors in the licensee testing facility's testing process, the licensee or other entity may re-collect and test specimens from any donor whose test results from the licensee testing facility may have been inaccurate.

(5) 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 are 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 permitted under § 26.75(h), positive test results from initial drug tests at the licensee testing facility may not be reported to licensee or other entity management. In addition, the licensee testing facility may not report results from validity screening or initial validity testing indicating that a specimen is of questionable validity or positive initial drug test results from specimens that are of questionable validity.

(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 and the SAE.

(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 § 26.717.

(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 assays, validity screening tests, 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-certified 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, as permitted by § 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 section 503 of Public Law 100-71, any employee of a licensee or other entity who is the subject of a drug test (or his or her representative designated under § 26.37(d)) shall, on 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, including, but not limited to, the relationships described in § 26.183(b), 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 a manual of standard operating 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 certify 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 adulterated, substituted, dilute, or invalid.

(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 the 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 and 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 a written manual of 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 HHS Secretary, 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.

(1) 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. When notified, the licensee or other entity shall ensure that an investigation is initiated to determine whether tampering has occurred.

(i) If the investigation determines that tampering has occurred, the licensee or other entity shall ensure that corrective actions are taken.

(ii) 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, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, if the licensee testing facility has retained the specimen in Bottle B, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen:

(i) The custody-and-control form does not contain information to identify the specimen collector and the collection site cannot provide conclusive evidence of the collector's identity;

(ii) The identification numbers on the specimen bottle seal(s) do not match the identification numbers on the custody-and-control form;

(iii) A specimen bottle seal is broken or shows evidence of tampering and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist;

(iv) The specimen appears to have leaked out of its sealed bottle and there is less than 15 mL remaining, and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist; or

(v) As required under § 26.165(f)(2).

(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 a copy of the custody-and-control form is packaged with the aliquot of a single specimen or Bottle B of a split specimen, as appropriate. Sealed and labeled specimen bottles and aliquots, 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 by 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 (42.8 ºF). 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 (-68 ºF) or less ensures that 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 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. The laboratory may not retain any information linking donors to specimens that are pooled for use in the internal quality control program.

§ 26.161 Cutoff levels for validity testing.

(a) *Validity test results*. Each validity test result for a specimen that the HHS-certified laboratory reports to the MRO as adulterated, substituted, dilute, or invalid must be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot. Licensees and other entities shall ensure that the HHS-certified laboratory is capable of conducting, and conducts, confirmatory testing for at least one oxidizing adulterant and any other adulterants specified by the licensee's or other entity's testing program. If initial validity test results indicate that the specimen is valid under the criteria in paragraphs (c) through (f) of this section, the HHS-certified laboratory need not perform confirmatory validity testing of the specimen.

(b) *Initial validity testing*. The HHS-certified laboratory shall perform initial validity testing of each specimen as follows:

(1) Determine the creatinine concentration;

(2) Determine the specific gravity of every specimen for which the creatinine concentration is less than 20 mg/dL;

(3) Determine the pH;

(4) Perform one or more initial validity tests for oxidizing adulterants; and

(5) Perform additional validity tests, the choice of which depends on the observed indicators or characteristics below, when the following conditions are observed:

(i) Abnormal physical characteristics;

(ii) Reactions or responses characteristic of an adulterant obtained during initial or

confirmatory drug tests (e.g., non-recovery of internal standards, unusual response); or

(iii) Possible unidentified interfering substance or adulterant.

(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 gas chromatography/mass spectrometry (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 the equivalent of 200 mcg/mL nitrite 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 [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	2000
Phencyclidine (PCP)	25
Amphetamines	1000

(2) At the licensee's or other entity's discretion, as documented in the FFD program policies and procedures, the licensee or other entity may require the HHS-certified laboratory to

conduct special analyses of dilute specimens as follows:

(i) If initial validity testing indicates that a specimen is dilute, the HHS-certified laboratory shall compare the responses of the dilute specimen to the cutoff calibrator in each of the drug classes;

(ii) If any response is equal to or greater than 50 percent of the cutoff, the HHS-certified laboratory shall conduct confirmatory testing of the specimen down to the LOD for those drugs and/or drug metabolites; and

(iii) The laboratory shall report the numerical values obtained from this special analysis 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 the licensee or other entity requires the special analysis of dilute specimens permitted in paragraph (a)(2) of this section 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 (PCP)	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) *Testing 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 positive or questionable validity test 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 HHS-certified laboratory or maintained in secure storage at the licensee testing facility, as required by § 26.135(a) and (c), as applicable. If the specimen in Bottle A is free of any evidence of drugs or drug metabolites, and is a valid specimen, then the licensee testing facility or HHS-certified laboratory may discard the specimens in Bottles A and B.

(b) *Donor request to MRO for a retest of a single specimen or testing Bottle B of a split specimen*. (1) For a confirmed positive, adulterated, or substituted result reported on a single specimen of 30 mL or more, or a specimen in Bottle A of a split specimen which the donor submitted to the licensee or other entity, a donor may request (through the MRO) that an aliquot from the single specimen or the split (Bottle B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory. For an invalid test result, a donor may not request that an aliquot from the single specimen or the split specimen in Bottle B be tested by a second HHS-certified laboratory.

(2) The MRO shall inform the donor that he or she may, within 3 business days of notification by the MRO of the confirmed positive, adulterated, or substituted test result, request the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen. The MRO shall provide the donor with specific instructions for making this request (i.e., providing telephone numbers or other contact information). The MRO shall have the ability to receive the donor's calls at all times during the 3-day period (e.g., by use of an answering

machine with a "time stamp" feature when there is no one in the MRO's office to answer the phone). The donor's request may be oral or in writing.

(3) The donor shall provide his or her permission for retesting an aliquot of the single specimen or the testing of Bottle B. Neither the licensee, MRO, NRC, nor any other entity may order retesting of the single specimen or testing of the specimen in Bottle B without the donor's written permission, except as permitted in § 26.185(l).

(4) If the donor has not requested a retest of an aliquot of a single specimen or a test of the split specimen (Bottle B) within 3 business days, the donor may present to the MRO information documenting that serious injury, illness, lack of actual notice of the confirmed test result, inability to contact the MRO (e.g., there was no one in the MRO's office and the answering machine was not working), or other circumstances unavoidably prevented the donor from making a timely request. If the MRO concludes from the donor's information that there was a legitimate reason for the donor's failure to contact the MRO within the 3 business days permitted, the MRO shall direct the retesting of an aliquot of the single specimen or the test of the split specimen (Bottle B) take place, as if the donor had made a timely request.

(5) As soon as reasonably practical and not more than 1 business day following the day of the donor's request, as permitted in paragraph (b)(3) or (b)(4) of this section, the MRO shall ensure that the HHS-certified laboratory forwards an aliquot of a single specimen, or that the HHS-certified laboratory (or licensee testing facility, as appropriate) forwards Bottle B of a split specimen, to a second HHS-certified laboratory that did not test the specimen in Bottle A.

(6) The HHS-certified laboratory that retests an aliquot of a single specimen or tests the specimen in Bottle B shall provide quantitative test results to the MRO and the MRO shall provide them to the donor.

(c) *Retesting a specimen for drugs*. (1) The second laboratory shall use its 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),

including retesting specimens that have been subject to the special analysis permitted in § 26.163(a)(2).

(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 reconfirm 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 required confirmatory validity test and criteria 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. 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 positive, adulterated, or substituted 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 positive, adulterated, or substituted 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 reconfirm any of the original positive, adulterated, or substituted test result(s), the licensee or other entity shall impose the appropriate sanctions specified in subpart D. 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 donor's personnel file 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 §§ 26.713 and 26.715 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 or the specimen in Bottle B 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 lost at the HHS-certified laboratory or licensee testing facility), the MRO shall cancel the test and inform the licensee or other entity that another collection is required under direct observation as soon as reasonably practical. 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 positive, adulterated, or substituted test result(s) and any temporary administrative action, and may not impose any sanctions on the donor for a cancelled test. If test results from the second specimen collected are positive, adulterated, or substituted 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 positive, adulterated, or substituted 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 one 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 to 1.5 mg/dL, a control in the range of 3 to 20 mg/dL, and a control in the range of 21 to 25 mg/dL; and

(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 1.0 to 1.5 mg/dL, and a control in the range of 3 to 4 mg/dL.

(2) Requirements for performing specific gravity tests:

(i) The refractometer must report and display the specific gravity to four decimal places, and must be interfaced with a laboratory information management system, 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; and

(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 to 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 to 12 to support the 3 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Dipsticks, colorimetric pH tests, and pH paper that have a narrow dynamic range and do not support the 2 to 12 pH cutoffs may be used only to determine whether initial validity tests must be performed;

(ii) 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;

(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 to 2.8;

(E) One control in the range of 3.2 to 4;

(F) One control in the range of 10 to 10.8; and

(G) One control in the range of 11.2 to 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 to 2.8; and

(D) One control in the range of 3.2 to 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 to 10.8; and

(D) One control in the range of 11.2 to 12; and

(vi) 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 to 2.8;

(D) One control in the range of 3.2 to 4;

(E) One control in the range of 4.5 to 9;

(F) One control in the range of 10 to 10.8;

(G) One control in the range of 11.2 to 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 as specified in § 26.161(c) and (f), 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; and

(ii) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory analytical run must include a calibrator at the appropriate cutoff concentration for the compound of interest as specified in § 26.161(c) and (f), 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 specimen), one control in the range of 200 to 400 mcg/mL, and one control in the range of 500 to 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; and

(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/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. For example, an HHS-certified laboratory may use immunoassay technique “A” for all drugs using the licensee’s or other entity’s cutoff levels, but specimens testing positive for amphetamines may also be tested using immunoassay technique “B” to eliminate any possible positives due to structural analogues; or, a valid analytical result cannot be obtained using immunoassay technique “A” and immunoassay technique “B” is used in an attempt to obtain a valid analytical result.

(3) Quality control samples for each analytical run of specimens for initial testing must include—

(i) Sample(s) certified to contain no drugs or drug metabolites (i.e., negative urine samples);

(ii) At least one positive control with a drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff;

(iii) At least one positive control with a drug(s) or drug metabolite(s) targeted at 25 percent below 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); and

(v) At least one control that appears to be a donor specimen to the laboratory analysts.

(4) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples, as defined by paragraphs (d)(3)(i) through (iv) of this section.

(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.

(3) 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) with a drug(s) or drug metabolite(s);

(iii) At least one positive control with a drug(s) or drug metabolite(s) 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) *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, as required under § 26.168, 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 each entity's 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 that corrective action is 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) If a false positive error occurs 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) If a false positive error occurs 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 adulterated, substituted, dilute, or invalid 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 responsible person. 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.

(g) *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.

(h) *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.

§ 26.168 Blind performance testing.

(a) 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 one percent of all specimens (up to a maximum of 100) or ten blind performance test samples, whichever is greater.

(3) 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.

(b) Approximately 60 percent of the blind performance test samples submitted to the laboratory must be positive for one or more drugs or drug metabolites per sample and submitted so that all of the drugs for which the FFD program is testing are included at least once each calendar quarter, except as follows:

(1) Licensees and other entities shall submit blind performance test samples that are

positive for marijuana metabolite at least two times each quarter; and

(2) In at least two quarters each year, licensees and other entities shall submit an additional blind performance test sample that is positive for cocaine instead of the required sample that is positive for PCP.

(c) The positive blind performance test samples must be positive for only those drugs for which the FFD program is testing and formulated at concentrations established in paragraph (g)(2) of this section.

(d) To challenge the HHS-certified laboratory's ability to limit false negatives, approximately 10 percent of the blind performance test samples submitted to the laboratory each quarter must be formulated at the concentrations established in paragraph (g)(3) of this section.

(e) 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 20 percent of the specimens submitted that quarter or at least three samples per quarter (one each that is adulterated, diluted, or substituted), whichever is greater. These samples must be formulated at the concentrations established in paragraphs (g)(4) through (g)(6) of this section.

(f) Approximately 10 percent of the blind performance test samples submitted to the laboratory each quarter must be negative, as specified in paragraph (g)(1) of this section.

(g) Licensees and other entities shall use only blind performance test samples that have been certified by the supplier to be—

(1) Negative. A negative blind performance test sample may not contain a measurable amount of a target drug analyte and must be certified by immunoassay and confirmatory testing;

(2) Drug positive. These samples must contain a measurable amount of the target drug or analyte in concentrations ranging between 150 and 200 percent of the initial cutoff values

and be certified by immunoassay and confirmatory testing to contain one or more drug(s) or drug metabolite(s);

(3) A false negative challenge. This blind performance test sample must contain a measurable amount of the target drug or analyte in concentrations ranging between 130 and 155 percent of the initial cutoff values;

(4) Adulterated. The adulterated blind performance test sample must have a pH of less than or equal to 2, or greater than or equal to 12, or a nitrite or other oxidant concentration equal to or greater than 500 mcg/mL, equal to or greater than 50 mcg/mL chromium (VI)-equivalents, or a halogen concentration equal to or greater than the LOD. Blind performance test samples for other adulterants must have adulterant concentrations equal to or greater than (or equal to or less than, as appropriate) the initial cutoff levels used by the licensee's or other entity's HHS-certified laboratory;

(5) Dilute. The dilute blind performance test sample must contain a creatinine concentration that is equal to or greater than 5 mg/dL but less than 20 mg/dL, and the specific gravity must be greater than 1.0010 but less than 1.0030; or

(6) Substituted. The substituted blind performance test sample must contain less than 2 mg/dL of creatinine, and the specific gravity must be less than or equal to 1.0010, or equal to or greater than 1.0200.

(h) In order to ensure that blind performance test samples continue to meet the criteria set forth in paragraph (g) of this section, licensees and other entities shall—

(1) Ensure that all blind performance test sample lots are placed in service by the supplier only after confirmation by an HHS-certified laboratory, and for no more than 6 months;

(2) Ensure that the supplier provides the expiration date for each blind performance test sample to ensure that each sample will have the expected value when it is submitted to and tested by a laboratory; and

(3) At a minimum, require the supplier to check each open lot bi-monthly (i.e., every two

months) to ensure that samples remaining in the lot do not fall below 130% of the initial cutoff test concentration established by the assay manufacturer. Thus, for example, a lot that was certified by an HHS-certified laboratory at 155% of the manufacturer's assay cutoff level, and was reported by the licensee's or other entity's HHS-certified laboratory to be at or above 130% of that standard is acceptable. A test that indicated a result below 130% of that standard would be unacceptable. Licensees and other entities shall discard blind performance test samples from any lot that is outside of these parameters and may not use any further samples from that lot.

(i) Licensees and other entities shall ensure that each blind performance test sample is indistinguishable to laboratory personnel from a donor's specimen, as follows:

(1) The licensee or other entity shall submit blind performance test samples to the laboratory using the same channels (i.e., from the licensee's or other entity's collection site or licensee testing facility, as appropriate) through which donors' specimens are sent to the laboratory;

(2) The collector and licensee testing facility personnel, as appropriate, shall use a custody-and-control form, place fictional initials on the specimen bottles' labels/seals, and indicate for the MRO on the MRO's copy that the specimen is a blind performance test sample; and

(3) The licensee or other entity shall ensure that all blind performance test samples include split samples, when the FFD program includes split specimen procedures.

§ 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) 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.

(c) 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 positive, adulterated, substituted, dilute, or invalid 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, dilute, or invalid specimen.

(1) The laboratory shall report all positive, adulterated, substituted, dilute, and invalid test results for each specimen to the MRO. For example, a specimen may be both adulterated and positive for one or more specific drugs.

(2) For a specimen that has a positive test result, the laboratory shall provide numerical values if the MRO requests such information. The MRO's request for positive confirmatory test results may be either a general request covering all such results or a specific case-by-case request. 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.

(3) For a specimen that has an adulterated or substituted test result, the laboratory 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 of the specific gravity test.

(4) 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. This 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.

(5) 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.

(d) The MRO and MRO staff may not disclose quantitative test results to a licensee or other entity, but shall report only whether the specimen was positive (and for which analyte), adulterated, substituted, dilute, invalid, or negative, except as permitted under § 26.37(b). This paragraph does not preclude either the HHS-certified laboratory or the MRO from providing program performance data, as required under § 26.717.

(e) 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 orally 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.

(f) 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 positive, adulterated, substituted, dilute, and invalid 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.

(g) For a specimen that has a positive, adulterated, substituted, dilute, or invalid 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.

(h) 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. 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 positive and dilute [including an indication as to whether the specimen was subject to the special analysis permitted in § 26.163(a)(2)];

(7) Total number of specimens reported as invalid; and

(8) Number of specimens reported as rejected for testing and the reason for the rejection.

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. Examples of relationships between laboratories and MROs that create conflicts of interest, or the appearance of such conflicts, include, but are not limited to—

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the licensee or other entity is to use, gives the licensee or other entity a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the licensee or other entity a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or

(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

(c) *Responsibilities*. The primary role of the MRO is to review and interpret positive, adulterated, substituted, invalid, and at the licensee's or other entity's discretion, dilute 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 positive, adulterated, substituted, invalid, or, at the licensee's or other entity's discretion, dilute 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 positive, adulterated, substituted, invalid, or dilute 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 under 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 under 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. Employees of a licensee or other entity who serve MRO staff functions may also perform other duties for the

licensee or other entity and need not be under the direction of the MRO while performing those other duties.

(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 while they are performing those functions, and those functions must be under the MRO's 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 as required by 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 positive, adulterated, substituted, invalid, and, at the licensee's

or other entity's discretion, dilute 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 positive, adulterated, substituted, invalid, or dilute test results nor request medical information from a donor. Only the MRO may request and review medical information related to a positive, adulterated, substituted, or invalid test result or other matter from a donor.

(iv) Staff may not report nor discuss with any individuals other than the MRO and other MRO staff any positive, adulterated, substituted, invalid, or dilute test results received from the HHS-certified laboratory before those results have been reviewed and confirmed by the MRO. Any MRO staff discussions of confirmed positive, adulterated, substituted, invalid, or dilute test results must be limited to discussions only with the licensee's or other entity's FFD program personnel and may not reveal quantitative test results or any personal medical information about the donor that the MRO may have obtained in the course of reviewing confirmatory test results from the HHS-certified laboratory.

§ 26.185 Determining a fitness-for-duty policy violation.

(a) *MRO review required*. A positive, adulterated, substituted, dilute, or invalid 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 positive, adulterated, substituted, and invalid 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 positive, adulterated, substituted, dilute, or invalid initial test results that are received from the HHS-certified laboratory to the licensee or other entity.

(c) *Discussion with the donor*. Before determining that a positive, adulterated, substituted, dilute, or invalid 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 positive, adulterated, substituted, dilute, or invalid 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 positive, adulterated, substituted, dilute, or invalid 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 1 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 positive, adulterated, substituted, dilute, or invalid test result or other occurrence directly with the donor, the donor may, on 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 positive or adulterated 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 on 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 on 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, and a clinical examination, if required under paragraph (g)(4) of this section, has been conducted, the MRO shall determine that the drug test results are positive and that the donor has violated the FFD policy.

(2) If the licensee or other entity requires the HHS-certified laboratory to conduct the special analysis of dilute specimens permitted in § 26.163(a)(2), the results of the special analysis are positive, the MRO determines that there is no legitimate medical explanation for the presence of the drug(s) or drug metabolite(s) in the specimen, and a clinical examination, if required under paragraph (g)(4) of this section, has been conducted under paragraph (j) of this section, the MRO shall determine whether the positive and dilute specimen is a refusal to test. If the MRO does not have sufficient reason to believe that the positive and dilute specimen is a subversion attempt, he or she shall determine that the drug test results are positive and that the donor has violated the FFD policy. When determining whether the donor has diluted the specimen in a subversion attempt, the MRO shall also consider the following circumstances, if

applicable:

(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; or

(iii) The collector observed conduct clearly and unequivocally indicating an attempt to dilute the specimen.

(3) If a dilute specimen was collected under direct observation, 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 as required by § 26.31(d)(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.

(5) An MRO review is not required for specimens that the HHS-certified laboratory reports as negative and dilute. The licensee or other entity may not take any administrative actions or impose any sanctions on a donor who submits a negative and 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 physician who is experienced and qualified in the medical issues involved, as verified by the MRO. Claims of excessive hydration, or claims based on 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. Any medical evidence must be submitted through a physician experienced and qualified in the medical issues involved, as verified by the MRO.

(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 a 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 confirmatory 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 confirmatory 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 confirmatory 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 confirmatory test result for opiates or 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 confirmatory 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 confirmatory 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 confirmatory 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 the MRO question the accuracy or scientific validity of a positive, adulterated, substituted, or invalid test result, only the MRO is authorized to order retesting of an aliquot of the original specimen or the analysis of any split specimen (Bottle B) in order to determine whether the FFD policy has been violated. 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 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 positive, adulterated, substituted or invalid 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 positive test results, the MRO may report an FFD policy violation to the licensee or other entity;

(2) If the second laboratory reconfirms any adulterated, substituted, or invalid 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 positive test results, the MRO shall report that no FFD policy violation has occurred; or

(4) If the second laboratory does not reconfirm the adulterated, substituted, or invalid validity test results, the MRO shall report that no FFD policy violation has occurred.

(o) *Re-authorization after a first violation for a 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 positive, adulterated, substituted, and invalid test results and, in instances when the MRO determines that there is no legitimate medical explanation for the test result(s), notify the licensee's or other entity's designated representative within 10 business days of an initial positive, adulterated, substituted, or invalid test result. The MRO shall notify the licensee or other entity of the results of his or her review 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]**, any SAEs on whom licensees and other entities rely to make determinations of fitness under this part shall meet the requirements of this section. An MRO who meets the requirements of this section may serve as both an MRO and as an SAE.

(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 or by the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse.

(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 duties

performed by the individuals who are subject to this subpart; 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 on request to NRC representatives, licensees, or other entities who are relying on or contemplating relying on the SAE's services, and to other individuals and entities, as required by § 26.37.

(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) After 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 entered when there are indications that an individual specified in § 26.4(a) through (e), and at the licensee's or other entity's discretion as specified in § 26.4(f) and (g), 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 on 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 consistently 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 under 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 positive, adulterated, substituted, or invalid 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 under a licensee's or other entity's FFD policy;

(3) Before an individual is granted authorization when potentially disqualifying FFD information is identified that has not previously been evaluated by another licensee or entity who is subject to this subpart; 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 (i.e., because of observed behavior or a physical condition) 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.

§ 26.201 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), and, if applicable, § 26.3(d). The requirements in §§ 26.203 and 26.207 through 26.111 apply to the individuals identified in § 26.4(a) through (c). In addition, the requirements in § 26.205 apply to the individuals identified in § 26.4(a).

§ 26.203 General provisions.

(a) *Policy*. Licensees shall establish a policy for the management of fatigue for all individuals who are subject to the licensee's FFD program 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 identified in § 26.4(a) through (c) 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 rights and 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 § 26.211(a)(2);

(2) Describe the process for implementing the controls required under § 26.205 for the individuals who are performing the duties listed in § 26.4(a);

(3) Describe the process to be followed in conducting fatigue assessments under § 26.211; and

(4) Describe the sanctions that the licensee may impose on an individual following a fatigue assessment, and the conditions and considerations for taking those sanctions.

(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 § 26.205;

(2) Records of shift schedules and shift cycles of individuals who are subject to the work hour controls in § 26.205;

(3) The documentation of waivers that is required in § 26.207(a)(4), including the bases for granting the waivers;

(4) The documentation of work hour reviews that is required in § 26.205(e)(3) and (e)(4); and

(5) The documentation of fatigue assessments that is required in § 26.211(f).

(e) *Reporting*. Licensees shall include the following information in a standard format in the annual FFD program performance report required under § 26.717:

(1) A summary for each nuclear power plant site of all instances during the previous calendar year when the licensee waived the work hour controls specified in § 26.205(d)(1) through (d)(5)(i) for individuals described in § 26.4(a). The summary must include only those waivers under which work was performed. If it was necessary to waive more than one work hour control during any single extended work period, the summary of instances must include each of the work hour controls that were waived during the period. For each category of individuals specified in § 26.4(a), the licensee shall report—

(i) The number of instances when each work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), and (d)(3)(i) through (d)(3)(iv) was waived for individuals not working on outage activities;

(ii) The number of instances when each work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(iv), and (d)(4) and (d)(5)(i) was

waived for individuals working on outage activities; and

(iii) A summary that shows the distribution of waiver use among the individuals within each category of individuals identified in § 26.4(a) (e.g., a table that shows the number of individuals that received only one waiver during the reporting period, the number of individuals that received a total of two waivers during the reporting period, etc.).

(2) A summary for each nuclear power plant site of instances of fatigue assessments that were conducted during the previous calendar year for any individual identified in § 26.4(a) through (c). The summary must include—

(i) The conditions under which each fatigue assessment was conducted (i.e., self-declaration, for cause, post-event, followup);

(ii) A statement of whether or not the individual was working on outage activities at the time of the self-declaration or condition resulting in the fatigue assessment;

(iii) The category of duties the individual was performing, if the individual was performing the duties described in § 26.4(a)(1) through (a)(5) at the time of the self-declaration or condition resulting in the fatigue assessment; and

(iv) The management actions, if any, resulting from each fatigue assessment.

(f) *Audits.* Licensees shall audit the management of worker fatigue as required by § 26.41.

§ 26.205 Work hours.

(a) *Individuals subject to work hour controls*. Any individual who performs duties identified in § 26.4(a)(1) through (a)(5) shall be subject to the requirements of this section.

(b) *Calculating work hours.* For the purposes of this section, a licensee shall calculate the work hours of individuals who are subject to this section as the amount of time the individuals perform duties for the licensee. Except as permitted by paragraphs (b)(1) through (b)(5) of this section, the calculated work hours must include all time performing duties for the

licensee, including all within-shift break times and rest periods during which there are no reasonable opportunities or accommodations appropriate for restorative sleep.

(1) Shift turnover. Licensees may exclude shift turnover from the calculation of an individual's work hours. 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.

(2) Within-shift break and rest periods. Licensees may exclude from the calculation of an individual's work hours only that portion of a break or rest period during which there is a reasonable opportunity and accommodations for restorative sleep (e.g., a nap).

(3) Beginning or resuming duties subject to work hour controls. If an individual begins or resumes performing for the licensee any of the duties listed in § 26.4(a) during the calculation period, the licensee shall include in the calculation of the individual's work hours all work hours worked for the licensee, including hours worked performing duties that are not listed in § 26.4(a), and control the individual's work hours under the requirements of paragraph (d) of this section.

(4) Unannounced emergency preparedness exercises and drills. Licensees may exclude from the calculation of an individual's work hours the time the individual works unscheduled work hours for the purpose of participating in the actual conduct of an unannounced emergency preparedness exercise or drill.

(5) Incidental duties performed off site. Licensees may exclude from the calculation of an individual's work hours unscheduled work performed off site (e.g., technical assistance provided by telephone from an individual's home) provided the total duration of the work does not exceed a nominal 30 minutes during any single break period. For the purposes of compliance with the minimum break requirements of paragraph (d)(2) of this section and the minimum day off requirements of paragraph (d)(3) through (d)(5) of this section, such duties do not constitute work periods or work shifts.

(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*. Licensees shall control the work hours of individuals who are subject to this section.

(1) Except as permitted in § 26.207, 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, at a minimum, the rest breaks specified in this paragraph. 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 one period of shift turnover at either the beginning or end of a shift but not both. Except as permitted in § 26.207, licensees shall ensure that individuals have, at a minimum—

(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; and

(ii) A 34-hour break in any 9-day period.

(3) Licensees shall ensure that individuals have, at a minimum, the number of days off specified in this paragraph. For the purposes of this subpart, a day off is defined as a calendar day during which an individual does not start a work shift. For the purposes of calculating the average number of days off required in this paragraph, the duration of the shift cycle may not exceed 6 weeks.

(i) Individuals who are working 8-hour shift schedules shall have at least 1 day off per week, averaged over the shift cycle;

(ii) Individuals who are working 10-hour shift schedules shall have at least 2 days off per week, averaged over the shift cycle;

(iii) Individuals who are working 12-hour shift schedules while performing the duties described in § 26.4(a)(1) through (a)(4) shall have at least 2.5 days off per week, averaged over the shift cycle; and

(iv) Individuals who are working 12-hour shift schedules while performing the duties described in § 26.4(a)(5), shall have at least 3 days off per week, averaged over the shift cycle.

(4) During the first 60 days of a unit outage, licensees need not meet the requirements of paragraph (d)(3) of this section for individuals specified in § 26.4(a)(1) through (a)(4), while those individuals are working on unit outage activities. However, the licensee shall ensure that these individuals have at least 3 days off in each successive (i.e., non-rolling) 15-day period;

(5) During the first 60 days of a unit outage, security system outage, or increased threat condition, licensees shall control the hours worked by individuals specified in § 26.4(a)(5) as follows:

(i) During the first 60 days of a unit outage or a planned security system outage, licensees need not meet the requirements of paragraph (d)(3) of this section. However, licensees shall ensure that these individuals have at least 4 days off in each successive (i.e., non-rolling) 15-day period; and

(ii) During the first 60 days of an unplanned security system outage or increased threat condition, licensees need not meet the requirements of either paragraph (d)(3) or (d)(5)(i) of this section;

(6) The 60-day periods in paragraphs (d)(4) and (d)(5) of this section may be extended for each individual in 7-day increments for each non-overlapping 7-day period the individual has worked not more than 48 hours during the unit or security system outage or increased threat condition, as applicable; and

(7) When an individual works for a licensee during two or more unit outages or security system outages (or a combination thereof), and the interval(s) between successive outages is less than 2 weeks, licensees shall implement the requirements in paragraphs (d)(4) through (d)(6) of this section based on the number of days that have elapsed since the first outage in the series began.

(e) *Reviews*. Licensees shall evaluate the effectiveness of their control of work hours of individuals who are subject to this section. At a minimum, licensees shall conduct the reviews twice per calendar year. The two reviews need not cover periods of equal duration but must collectively cover the entire calendar year. If any plant or security system outages or increased threat conditions occurred since the licensee completed the most recent review, the licensee shall include in the review an evaluation of the control of work hours during the outages or increased threat conditions. Licensees shall complete the review within 30 days of the end of the review period. Licensees shall—

(1) Review the actual work hours and performance of individuals who are subject to this section for consistency with the requirements of § 26.205(c). At a minimum, this review must address—

(i) Individuals whose actual hours worked during the review period exceeded an average of 54 hours per week in any shift cycle while the individuals' work hours are subject to the requirements of § 26.205(d)(3);

(ii) Individuals who were granted more than one waiver during the review period; and

(iii) Individuals who were assessed for fatigue under § 26.201 during the review period.

(2) Review individuals' hours worked and the waivers under which work was performed to evaluate 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.

§ 26.207 Waivers and exceptions.

(a) *Waivers*. Licensees may grant a waiver of the work hour controls in § 26.205(d)(1) through (d)(5)(i), as follows:

(1) To grant a waiver, the licensee shall meet both of the following requirements:

(i) 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 site security, or a site senior-level manager with requisite signature authority makes either determination; and

(ii) A supervisor 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. The supervisor performing the assessment shall be trained as required by §§ 26.29 and 26.203(c) and shall be qualified to direct the work to be performed by the individual. If there is no supervisor on site who is qualified to direct the work, the assessment may be performed by a supervisor who is qualified to provide oversight of the work to be performed by the individual. 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;

(2) To the extent practicable, licensees shall rely on the granting of waivers only to address circumstances that could not have been reasonably controlled;

(3) Licensees shall ensure that the timing of the face-to-face supervisory assessment that is required by paragraph (a)(1)(ii) 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 4 hours before the individual begins performing any work under the waiver; and

(4) 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 paragraphs (a)(1)(i) and (ii) of this section.

(b) *Force-on-force tactical exercises*. For the purposes of compliance with the minimum days off requirements of § 26.205(d)(3), licensees may exclude shifts worked by security personnel during the actual conduct of NRC-evaluated force-on-force tactical exercises when calculating the individual's number of days off.

(c) *Common defense and security.* When informed in writing by the NRC that the requirements of § 26.205, or any subset thereof, are waived for security personnel to ensure the common defense and security, licensees need not meet the specified requirements of § 26.205 for the duration of the period defined by the NRC.

(d) *Plant emergencies*. Licensees need not meet the requirements of § 26.205(c) and (d) during declared emergencies, as defined in the licensee's emergency plan.

§ 26.209 Self-declarations.

(a) If an individual is performing, or being assessed for, work under a waiver of the requirements contained in § 26.205(d)(1) through (d)(5)(i) 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 § 26.4(a), 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 § 26.4(a) until relieved, the licensee shall immediately take action to relieve the individual.

(b) Following a self-declaration, as described in paragraph (a) of this section, the licensee—

(1) May reassign the individual to duties other than those listed in § 26.4(a), but only if the results of a fatigue assessment, conducted under the requirements of § 26.211, 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 break of at least 10 hours before the individual returns to performing any duties listed in § 26.4(a).

§ 26.211 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 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 duties.

(b) Only supervisors and FFD program personnel who are trained under §§ 26.29 and 26.203(c) may conduct a fatigue assessment. The fatigue assessment must be conducted 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 (on site) 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 (on site) the work activities during which the event

occurred; and

(iii) Evaluated or approved a waiver of the limits specified in § 26.205(d)(1) through (d)(5)(i) for any of the individuals who were performing or directing (on site) 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 has 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 § 26.205(d)(1) or that the individual has had the minimum breaks required in § 26.205(d)(2) or minimum days off required in § 26.205(d)(3) through (d)(5), 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 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—[Reserved]

Subpart K—FFD Program for Construction

§ 26.401 General.

(a) At the licensee's or other entity's discretion, a licensee or other entity in § 26.3(c) may establish, implement, and maintain an FFD program that meets the requirements of this subpart to apply to the individuals specified in § 26.4(f). If a licensee or other entity in § 26.3(c) does not elect to implement an FFD program that meets the requirements of this subpart, the individuals specified in § 26.4(f) shall be subject to an FFD program that meets the requirements of subparts A through H, N, and O of this part.

(b) Licensees and other entities who intend to implement an FFD program under this subpart shall submit an FFD program plan to the NRC for review and approval as part of the license or permit application.

(c) Nothing in this subpart prohibits the licensees and other entities in § 26.3(c) from subjecting the individuals in § 26.4(f) to an FFD program that meets all of the requirements of this part or FFD program elements that meet all of the applicable requirements of this part.

§ 26.403 Written policy and procedures.

(a) Licensees and other entities who implement an FFD program under this subpart shall ensure that a clear, concise, written FFD policy statement is provided to individuals who are subject to the program. 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.

(b) Licensees and other entities shall develop, implement, and maintain written procedures that address the following topics:

(1) The methods and techniques to be used in testing for drugs and alcohol, including

procedures for protecting the privacy 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) The immediate and followup actions that will be taken, and the procedures to be used, in those cases in which individuals who are subject to the FFD program are determined to have—

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

(ii) Consumed alcohol to excess before or while constructing safety- or security-related SSCs, as determined by a test that accurately 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; and

(3) The process to be followed if an individual's behavior or condition raises a concern regarding the possible use, sale, or possession of illegal drugs on or off site; the possible use or possession of alcohol while constructing safety- or security-related SSCs; or impairment from any cause which in any way could adversely affect the individual's ability to safely and competently perform his or her duties.

§ 26.405 Drug and alcohol testing.

(a) To provide means to deter and detect substance abuse, licensees and other entities who implement an FFD program under this subpart shall perform drug and alcohol testing that complies with the requirements of this section.

(b) If the licensee or other entity elects to impose random testing for drugs and alcohol on the individuals identified in § 26.4(f), random testing must—

(1) Be administered in a manner that provides reasonable assurance that individuals are

unable to predict the time periods during which specimens will be collected;

(2) 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;

(3) Ensure that all individuals in the population that is subject to random testing on a given day have an equal probability of being selected and tested; and

(4) Provide that an individual completing a test is immediately eligible for another random test.

(c) Individuals identified in § 26.4(f) shall be subject to drug and alcohol testing under the following conditions:

(1) Pre-assignment. Before assignment to construct safety- or security-related SSCs;

(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;

(3) Post-accident. As soon as practical after an event involving a human error that was committed by an individual specified in § 26.4(f), where the human error may have caused or contributed to the accident. 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 1904.7, 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; or

(ii) Significant damage, during construction, to any safety- or security-related SSC; and

(4) Followup. As part of a followup plan to verify an individual's continued abstinence from substance abuse.

(d) At a minimum, licensees and other entities shall test specimens for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol, at the cutoff levels specified in this part or comparable cutoff levels, if specimens other than urine are collected for drug testing. Urine specimens collected for drug testing must be subject to validity testing.

(e) The specimen collection and drug and alcohol testing procedures of FFD programs under this subpart must protect the donor's privacy and the integrity of the specimen, and implement stringent quality controls to ensure that test results are valid and attributable to the correct individual. At the licensee's or other entity's discretion, specimen collections and alcohol testing may be conducted at a local hospital or other facility under the specimen collection and alcohol testing requirements of 49 CFR part 40 and subsequent amendments thereto.

(f) Testing of urine specimens for drugs and validity, except validity screening and initial drug and validity tests that may be performed by licensee testing facilities, must be performed in a laboratory that is certified by HHS for that purpose, consistent with its standards and procedures for certification. Any initial drug test performed by a licensee or other entity subject to this subpart must use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. Urine specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results must be subject to confirmatory testing by the HHS-certified laboratory, except for invalid specimens that cannot be tested. Other specimens that yield positive initial drug test results must be subject to confirmatory testing by a

laboratory that meets stringent quality control requirements that are comparable to those required for certification by the HHS.

(g) Licensees and other entities shall provide for an MRO review of positive, adulterated, substituted, and invalid confirmatory drug and validity test results to determine whether the donor has violated the FFD policy, before reporting the results to the individual designated by the licensee or other entity to perform the suitability and fitness evaluations required under § 26.419.

§ 26.406 Fitness monitoring.

(a) The requirements in this section apply only if a licensee or other entity does not elect to subject the individuals specified in § 26.4(f) to random testing for drugs and alcohol under § 26.405(b).

(b) Licensees and other entities shall implement a fitness monitoring program to deter substance abuse and detect indications of possible use, sale, or possession of illegal drugs; use or possession of alcohol while constructing safety- or security-related SSCs; or impairment from any cause that if left unattended may result in a risk to public health and safety or the common defense and security.

(c) Licensees and other entities shall establish procedures that monitors shall follow in response to the indications and actions specified in paragraph (a) of this section and train the monitors to implement the program.

(d) Licensees and other entities shall ensure that the fitness of individuals specified in § 26.4(f) is monitored effectively while the individuals are constructing safety- and security-related SSCs, commensurate with the potential risk to public health and safety and the common defense and security imposed by the construction activity. To achieve this objective, licensees and other entities shall consider the number and placement of monitors required, the necessary ratio of monitors to individuals specified in § 26.4(f), and the frequency with which the

individuals specified in § 26.4(f) shall be monitored while constructing each safety- or security-related SSC.

§ 26.407 Behavioral observation.

While the individuals specified in § 26.4(f) are constructing safety- or security-related SSCs, licensees and other entities shall ensure that these individuals are subject to behavioral observation, except if the licensee or other entity has implemented a fitness monitoring program under § 26.406.

§ 26.409 Sanctions.

Licensees and other entities who implement an FFD program under this subpart shall establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.4(f) from being assigned to construct safety- or security-related SSCs unless or until the licensee or other entity determines that the individual's condition or behavior does not pose a potential risk to public health and safety or the common defense and security.

§ 26.411 Protection of information.

(a) Licensees and other entities who collect personal information about an individual for the purpose of complying with this subpart shall establish and maintain a system of files and procedures to protect the personal information. FFD programs must 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 subpart before disclosing the personal information, except for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.413.

§ 26.413 Review process.

Licensees and other entities who implement an FFD program under this subpart shall establish and implement procedures for the review of a determination that an individual in § 26.4(f) 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.

§ 26.415 Audits.

(a) Licensees and other entities who implement an FFD program under this subpart shall ensure that audits are performed to assure the continuing effectiveness of the FFD program, including FFD program elements that are provided by C/Vs, and the FFD programs of C/Vs that are accepted by the licensee or other entity.

(b) Each licensee and other entity shall ensure that these programs are audited at a frequency that assures their continuing effectiveness and that corrective actions are taken to resolve any problems identified. Licensees and entities may conduct joint audits, or accept audits of C/Vs conducted by others, so long as the audit addresses the relevant C/Vs' services.

(c) Licensees and other entities need not audit HHS-certified laboratories or the specimen collection and alcohol testing services 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), on which licensees and other entities may rely to meet the drug and alcohol testing requirements of this subpart.

§ 26.417 Recordkeeping and reporting.

(a) Licensees and other entities who implement FFD programs under this subpart shall ensure that records pertaining to the administration of the program, which may be stored and archived electronically, are maintained so that they are available for NRC inspection purposes

and for any legal proceedings resulting from the administration of the program.

(b) Licensees and other entities shall make the following reports:

(1) Reports to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to this subpart. These events must be reported under this subpart, rather than under the provisions of 10 CFR 73.71; and

(2) Annual program performance reports for the FFD program.

§ 26.419 Suitability and fitness evaluations.

Licensees and other entities who implement FFD programs under this subpart shall develop, implement, and maintain procedures for evaluating whether to assign individuals to construct safety- and security-related SSCs. These procedures must provide reasonable assurance that the individuals are fit to safely and competently perform their duties, and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse.

Subpart L—[Reserved]

SubpartM—[Reserved]

Subpart N—Recordkeeping and Reporting Requirements

§ 26.709 Applicability.

The requirements of this subpart apply to the FFD programs of licensees and other entities specified in § 26.3, except for FFD programs that are implemented under subpart K of

this part.

§ 26.711 General provisions.

(a) Each licensee and other entity 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.

(c) The licensees and other entities specified in § 26.4(a) and (d), as applicable, shall inform each individual of his or her right to review information about the individual that is collected and maintained under this part to assure its accuracy. Licensees and other entities shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is documented by licensees and other entities about the individual.

(d) Licensees and other entities shall ensure that only correct and complete information about individuals is retained and shared with other licensees and entities. If, for any reason, the shared information used for determining an individual's eligibility for authorization under this part changes or new information is developed about the individual, licensees and other entities shall correct or augment the shared information contained in the records. If the changed or developed information has implications for adversely affecting an individual's eligibility for authorization, a licensee and other entity specified in § 26.4(a) and (d), as

applicable, who has discovered the incorrect information, or develops new information, shall inform the reviewing official of any FFD program under which the individual is maintaining authorization of the updated information on the day of discovery. The reviewing official shall evaluate the information and take appropriate actions, which may include denial or unfavorable termination of the individual's authorization.

§ 26.713 Recordkeeping requirements for licensees and other entities.

(a) Each licensee and other entity who is subject to this subpart 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, including any recommendations for treatment and followup testing plans.

(b) Each licensee and other entity who is subject to this subpart 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, on 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 26.203(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)(i), 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 time the FFD program follows these practices or until the completion of all related legal proceedings, whichever is later.

§ 26.715 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 who are subject to this subpart, 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 on 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 quality control or 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.

§ 26.717 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 subpart.

(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, tests for drugs not included in the HHS panel, and any special analyses of dilute specimens permitted under § 26.163(a)(2);

(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.

§ 26.719 Reporting requirements.

(a) *Required reports*. Each licensee and entity who is subject to this subpart 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 duties that require the individual to be subject to the FFD program;

(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 duties that require them to be subject to the FFD program.

(c) *Drug and alcohol testing errors*. (1) Within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered in performance testing at either a licensee testing facility or an HHS-certified laboratory, in the testing of quality control or 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) If a false positive error occurs 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) If a false negative error occurs on a quality assurance check of validity screening tests, as required in § 26.137(b), 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 O—Inspections, Violations, and Penalties

§ 26.821 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 under 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.

§ 26.823 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.

§ 26.825 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 the 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, 26.201, 26.823, and 26.825.

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Dated at Rockville, Maryland, this XX day of XXX, 200X.

For the Nuclear Regulatory Commission.

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Annette Vietti-Cook,

Secretary of the Commission.

Note: This appendix will not appear in The Code of Federal Regulations.

Appendix A to this Document — Derivation and Distribution Tables for Part 26.

TABLE 1.—DERIVATION TABLE FOR PART 26

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 (c)
26.3 (d)	26.23 (a) (1)
26.3 (e)	26.2 (b)
26.4 (a)	26.2 (a) and 26.2 (d)
26.4 (b)	26.2 (a) and 26.2 (d)
26.4 (c)	26.2 (a) and 26.2 (d)
26.4 (d)	26.2 (a) and 26.2 (d)
26.4 (e)	NEW
26.4 (f)	NEW
26.4 (g)	NEW
26.4 (h)	NEW
26.4 (i) (1)	26.20 (a)
26.4 (i) (2)	26.2 (b) first sentence
26.4 (i) (3)	26.2 (b) first sentence
26.4 (i) (4)	NEW
26.4 (j)	NEW
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
26.27 (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)

New Section	Based on
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) (1)	26.20 (c)
26.27 (c) (2)	26.20 (d)
26.27 (c) (3)	26.20 (e)
26.27 (c) (4)	NEW
26.27 (d)	26.20 (f)
26.29 (a)	26.21 (a) (1)-(5); 26.22 (a) (1)-(5); 26.22 (b)
26.29 (b)	NEW
26.29 (c)	26.21(b) and 26.21 (c)
26.31	26.24
26.31 (a)	26.24 (a)
26.31 (b)	Section 2.3 in Appendix A to Part 26
26.31 (b) (1)	First paragraph, Section 2.3 in Appendix A to Part 26
26.31 (b) (1) (i)	Section 2.3 (2)
26.31 (b) (1) (ii)	Section 2.3 (1)
26.31 (b) (1) (iii)	Section 2.3 (1)
26.31 (b) (1) (iv)	NEW
26.31 (b) (1) (v)	Section 2.3 (3)
26.31 (b) (2)	NEW
26.31 (c)	26.24 (a) (1)-(4)
26.31 (c) (1)	26.24 (a) (1)
26.31 (c) (2)	26.24 (a) (3)
26.31 (c) (3)	26.24 (a) (3)
26.31 (c) (4)	26.24 (a) (4)
26.31 (c) (5)	26.24 (a) (2)
26.31 (d)	NEW
26.31 (d) (1)	Section 2.1 (a) in Appendix A to Part 26
26.31 (d) (1) (i) (A)	26.24 (c)
26.31 (d) (1) (i) (B)	26.24 (c)
26.31 (d) (1) (i) (C)	Section 2.1 (c)
26.31 (d) (1) (i) (D)	26.31 (d) (1) (i) (C)
26.31 (d) (1) (ii)	Section 2.1 (b) and 26.31 (d) (1) (i) (D)
26.31 (d) (1) (iii)	NEW
26.31 (d) (2)	26.24 (a)
26.31 (d) (3)	NEW
26.31 (d) (3) (i)	Appendix A Subpart A 1.1 (3); 26.24 (f); Appendix A Subpart B 2.8 (e); 2.8 (a) and (b)
26.31 (d) (3) (ii)	26.24 (d) (1)
26.31 (d) (3) (iii)	Sections 2.7 (e) (1) and (f) (2)
26.31 (d) (3) (iii) (A)	26.24 (b)
26.31 (d) (3) (iii) (B)	NEW
26.31 (d) (3) (iii) (C)	NEW
26.31 (d) (4)	26.24 (g)
26.31 (d) (5)	NEW
26.31 (d) (6)	Section 2.1 (d)
26.33	26.22
26.35	26.25

New Section	Based on
26.37	26.29
26.39	26.27
26.41 (a)	26.80 (a)
26.41 (b)	26.80 (a)
26.41 (c)	26.80 (a); Appendix A Subpart B 2.7 (m)
26.41 (d)	Section 2.7 (m)
26.41 (e)	26.80 (b)
26.41 (f)	26.80 (c)
26.41 (g)	26.80 (a)
26.51	26.1
26.53	NEW
26.55 (a)	NEW
26.55 (b)	NEW
26.57 (a)	NEW
26.57 (b)	NEW
26.59	NEW
26.61	26.27 (a) (1)
26.61 (a)	NEW
26.61 (b)	NEW
26.61 (c)	NEW
26.61 (d)	26.27 (a) (4)
26.63	26.27(a) (2)
26.63 (a)	NEW
26.63 (b)	NEW
26.63 (c)	NEW
26.63 (d)	NEW
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	26.24 (a) (1)
26.65 (a)	NEW
26.65 (b)	NEW
26.65 (c)	NEW
26.65 (d)	NEW
26.65 (e)	NEW
26.65 (f)	NEW
26.65 (g)	NEW
26.67 (a)	NEW
26.67 (b)	NEW
26.67 (c)	NEW
26.69	26.27 (b) (4)
26.69 (a)	NEW; 26.27 (b) (2)
26.69 (b) (1)	NEW
26.69 (b) (2)	NEW; 26.27 (b) (2)
26.69 (b) (3)	26.27 (b) (4)
26.69 (b) (4)	26.27 (b) (2)
26.69 (b) (5)	NEW
26.69 (b) (6)	26.27 (b) (4)
26.69 (b) (7)	NEW
26.69 (c) (1)	NEW

New Section	Based on
26.69 (c) (2)	NEW
26.69 (c) (3)	NEW
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
26.73	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)
26.75 (i)	26.24 (d) (2)
26.77	26.26 (b) (1)
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)
26.83 (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)
26.85 (d)	Appendix A Subpart B 2.7 (o) (5)
26.85 (e)	NEW
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)	NEW
26.87 (e) (2)	Appendix A Subpart B 2.4 (g) (1) (2nd sentence)
26.87 (e) (3)	NEW
26.87 (f) (1)	Appendix A Subpart B 2.4 (c) (1)
26.87 (f) (2)	Appendix A Subpart B 2.4 (g) (10) (3rd sentence)
26.87 (f) (3)	Appendix A Subpart B 2.4 (g) (10) (2nd sentence)
26.87 (f) (4)	Appendix A Subpart B 2.4 (g) (10) and new material
26.87 (f) (5)	Appendix A Subpart B 2.4 (c) (2)
26.89 (a)	Appendix A Subpart B 2.4 (g) (3)
26.89 (b)	Appendix A Subpart B 2.4 (g) (2)
26.89 (b) (1)	Appendix A Subpart B 2.4 (g) (2)

New Section	Based on
26.89 (b) (2)	Appendix A Subpart B 2.4 (g) (2)
26.89 (b) (3)	NEW
26.89 (b) (4)	Appendix A Subpart B 2.4 (g) (4) and (g) (23) (ii)
26.89 (c)	NEW
26.89 (d)	Appendix A Subpart B 2.4 (e)
26.91 (a)	Appendix A Subpart B 2.7 (o) (3) (ii)
26.91 (b)	Appendix A Subpart B 2.7 (o) (3) (ii)
26.91 (c)	NEW
26.91 (d)	NEW
26.91 (e)	NEW
26.93	Appendix A Subpart B 2.4 (g) (18) and new material
26.95	Appendix A Subpart B 2.4 (g) (18) and new material
26.97	NEW
26.99	26.24 (g) and Appendix A Subpart B 2.7 (e) (1)
26.101	Appendix A Subpart B 2.4 (g) (18) and new material
26.103	26.24 (g), Appendix A Subpart B 2.7(f) (2), and new material
26.105 (a)	Appendix A Subpart B 2.4 (g) (5)
26.105 (b)	NEW
26.105 (c)	Appendix A Subpart B 2.4 (g) (6)
26.105 (d)	Appendix A Subpart B 2.4 (g) (7)
26.105 (e)	NEW
26.107	Appendix A Subpart B 2.4 (g) and new material
26.109	Appendix A Subpart B 2.4 and new material
26.111 (a)	Appendix A Subpart B 2.4 (g) (13) and (g) (14)
26.111 (b)	Appendix A Subpart B 2.4 (g) (15)
26.111 (c)	NEW
26.111 (d)	Appendix A Subpart B 2.4 (g) (16)
26.111 (e)	NEW
26.111 (f)	NEW
26.113 (a)	NEW
26.113 (b)	Appendix A Subpart B 2.4 (g) (20) and 2.7 (j)
26.113 (c)	NEW
26.115 (a) (1)	Appendix A Subpart B 2.4 (f) (2)
26.115 (a) (2)	Appendix A Subpart B 2.4 (f) (1) and (g) (14)
26.115 (a) (3)	Appendix A Subpart B 2.4 (f) (3)
26.115 (a) (4)	Appendix A Subpart B 2.4 (f) (4)
26.115 (b)	Appendix A Subpart B 2.4 (g) (25)
26.115 (c)	NEW
26.115 (d)	NEW
26.115 (e)	Appendix A Subpart A 1.2 and Subpart B 2.4
26.115 (f)	NEW
26.117 (a)	Appendix A Subpart B 2.4 (g) (20)
26.117 (b)	Appendix A Subpart B 2.4 (g) (21)
26.117 (c)	Appendix A Subpart B 2.4 (g) (22)
26.117 (d)	Appendix A Subpart B 2.4 (g) (23)
26.117 (e)	Appendix A Subpart B 2.4 (g) (26)
26.117 (f)	Appendix A Subpart B 2.4 (g) (27)

New Section	Based on
26.117 (g)	Appendix A Subpart B 2.4 (g) (28)
26.117 (h)	Appendix A Subpart B 2.4 (c) (2)
26.117 (i)	Appendix A Subpart B 2.7 (i)
26.117 (j)	Appendix A Subpart B 2.4 (1) and 2.7 (c)_
26.117 (k)	Appendix A Subpart B 2.4 (h)
26.119	NEW
26.121	NEW
26.123	Appendix A Subpart B 2.7 (l) (2)
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 2.7 (a) (2) and 2.4 (d)
26.127 (c)	Appendix A Subpart B 2.7 (o) (1)
26.127 (d)	Appendix A Subpart B 2.7 (o) (3) (iii)
26.127 (e)	Appendix A Subpart B 2.7 (o) (4)
26.129 (a)	Appendix A Subpart B 2.7 (a) (1)
26.129 (b)	Appendix A Subpart B 2.2 (b) (1)
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)	Appendix A Subpart B 2.4 (i)
26.131	NEW
26.133	Appendix A Subpart B 2.7 (e) (1)
26.135 (a)	Appendix A Subpart B 2.7 (j)
26.135 (b)	Appendix A Subpart B 2.7 (j)
25.135 (c)	Appendix A Subpart B 2.7 (h)
26.137	Appendix A Subpart B 2.8 (a)
26.137 (e) (4-5)	Appendix A Subpart B 2.8 (b)
26.137 (e) (6-7)	Appendix A Subpart B 2.8 (c)
26.137 (f)	NEW
26.137 (g)	Appendix A Subpart B 2.7 (o) (3) (i)
26.137 (h)	Appendix A Subpart B 2.7 (o) (2)
26.139 (a)	Appendix A Subpart B 2.7 (g) (2)
26.139 (b)	26.24 (d) (1)
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), Appendix A Subpart A 1.1(3) and Subpart D 4.1 (a)
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 D 4.1 (b)
26.153 (e)	Appendix A Subpart B 2.7 (m)

New Section	Based on
26.153 (f) (1)	Appendix A Subpart B 2.7 (l)(1)
26.153 (f) (2)	Appendix A Subpart B 2.7 (o)(5)
26.153 (f) (3)	Appendix A Subpart C 3.1
26.153 (f) (4)	Appendix A Subpart C 3.2
26.153 (f) (5)	NEW
26.153 (f) (6)	Appendix A Subpart B 2.7 (m)
26.153 (g)	NEW
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 2.4 (d) and 2.7 (a)(2)
26.157 (c)	Appendix A Subpart B 2.7 (o) (1)
26.157 (d)	Appendix A Subpart B 2.2 (o) (3) (iii)
26.157 (e)	Appendix A Subpart B 2.7 (o) (4)
26.159 (a)	Appendix A Subpart B 2.7 (a) (1)
26.159 (b)	Appendix A Subpart B 2.7 (b) (1)
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)	Appendix A Subpart B 2.4 (i)
26.159 (h)	NEW
26.159 (i)	Appendix A Subpart B 2.7 (h)
26.159 (j)	NEW
26.161	NEW
26.163 (a)	Appendix A Subpart B 2.7 (e)
26.163 (a) (2)	NEW
26.163 (b)	Appendix A Subpart B 2.7 (f)
26.165 (a)	26.24 (f) and Appendix A Subpart B 2.7 (j)
26.165 (b)	Appendix A Subpart B 2.7 (j) and new material
26.165 (c)	Appendix A Subpart B 2.7 (i)
26.165 (c) (1)	NEW
26.165 (c) (2)	Appendix A Subpart B 2.7 (i)
26.165 (c) (3)	NEW
26.165 (c) (4)	Appendix A Subpart B 2.7 (j) (last sentence)
26.165 (d)	NEW
26.165 (e)	NEW
26.165 (f)	NEW
26.167 (a)	Appendix A Subpart B 2.8 (a) and (d)
26.167 (b)	Appendix A Subpart B 2.8 (c) and (d) and new material
26.167 (c)	NEW
26.167 (d) (1)	Appendix A Subpart B 2.7 (e) (1)
26.167 (d) (2)	NEW
26.167 (d) (3)	Appendix A Subpart B 2.8 (c)
26.167 (e)	Appendix A Subpart B 2.7 (f) (2) and 2.8 (d)
26.167 (f)	Appendix A Subpart B 2.8 (e) (4) - (e) (6)
26.167 (g)	Appendix A Subpart B 2.7 (o) (3) (i)
26.167 (h)	Appendix A Subpart B 2.7 (o) (2)
26.168	Appendix A Subpart B 2.8 (e) and new materia;
26.169	Appendix A Subpart B 2.7 (g) (substantially revised)

New Section	Based on
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)	Appendix A Subpart B 2.9 (b)
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 (b)
26.185 (c)	Appendix A Subpart B 2.9 (c)
26.185 (d)	NEW
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)
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
26.201	NEW
26.203	NEW
26.205	NEW
26.207	NEW
26.209	NEW
26.211	NEW
26.401	26.2 (c)
26.403	26.2 (c)
26.405	26.2 (c)
26.407	26.2 (c)
26.409	26.2 (c)
26.411	26.2 (c)
26.413	26.2 (c)
26.415	26.2 (c)
26.417	26.2 (c)
26.419	26.2 (c)
26.709	NEW
26.711	NEW

26.713 (a) (1)	26.71 (a)
26.713 (a) (2)	26.71 (b)
26.713 (a) (3)	NEW
26.713 (a) (4)	NEW
26.713 (b)	26.21 (b); 26.22 (c); 26.80 (c)
26.713 (c)	26.71 (c)
26.713 (d)	26.20
26.713 (e)	26.23 (a)
26.713 (f)	NEW
26.713 (g)	NEW
26.715 (a)	Appendix A, Section 2.7 (n)
26.715 (b) (1)-(14)	NEW
26.717	26.71 (d)
26.719 (a)-(b)	26.73
26.719 (c) (1)	Appendix A Subpart B 2.8 (e) (4)
26.719 (c) (2)	Appendix A Subpart B 2.8 (e) (5)
26.719 (c) (3)	NEW
26.719 (d)	NEW
26.821	26.70
26.823	26.90
26.825	26.91

TABLE 2.—DISTRIBUTION TABLE FOR PART 26

Former section	*Replaced by:*
26.1 (from beginning to “programs”)	26.1
26.1 (following “programs”)	Deleted
26.2 (a) (first clause)	26.3 (a)
26.2 (a) (balance of 1st sentence)	26.3 (b) first clause
26.2 (a) (2nd sentence)	26.21 (1st sentence)
26.2 (a) (3rd sentence to end)	26.4 (a), (b), (c), and (d)
26.2 (b) (1st sentence)	26.4 (i) (2) and (3)
26.2 (b) (2nd sentence to end)	26.3 (e)
26.2 (c) (1st sentence)	26.3 (c); Subpart K
26.2 (c) (from “shall implement” to end)	Subpart K
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)	26.713 (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)	26.713 (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) (1)-(4)	26.31 (c) (substantially revised)

Former section	*Replaced by:*
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) (2) and requirements in Subpart G
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	26.721
26.71	26.711, 26.713, and 26.715
26.73	26.719 (substantially revised)
26.80	26.41 (substantially revised)
26.90	26.723
26.91	26.725
Appendix A Subpart A, 1.1 (1)	26.3
Appendix A Subpart A, 1.1 (3)	Subparts F and G
Appendix A Subpart A, 1.2	26.5, and 26.115(e)
Appendix A Subpart B, 2.1 (a)	26.31 (d) (1)
Appendix A Subpart B, 2.1 (b)	26.31 (d) (1) (ii)
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 and 26.157 (b)
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 and 26.115 (e)
Appendix A Subpart B.2.4 (c)	26.87 (d) and (f), 26.117 (h)
Appendix A Subpart B 2.4 (d)	26.117 and 26.127 (b)
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

Former section	*Replaced by:*
Appendix A Subpart B 2.4 (g) (1) through (g) (25)	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)	26.129 (d) and 26.157
Appendix A Subpart B 2.4 (i)	26.117 (j), 26.129 (h) and 26.159
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 (c) and 26.155 (c)
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
Appendix A Subpart B 2.7 (c)	26.117 (j), 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 26.131 and 26.161 and initial cutoff levels in 26.133 and 26.163 (a)
Appendix A Subpart B 2.7 (f)	26.103, 26.115 (a), 26.163 (b), 26.167 and 26.169
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 (h)
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)	26.117 (i) and 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)	26.123 and 26.153
Appendix A Subpart B 2.7 (m)	26.87 (c), 26.153 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)

Former section	***Replaced by:***
Appendix A Subpart B 2.7 (o) (2), (o) (3), and (o) (4)	26.91, 26.127, 26.137, 26.157 and 26.167
Appendix A Subpart B 2.7 (o) (5)	26.85 (d), 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 and 26.167
Appendix A Subpart B 2.8 (e) (4), (e) (5), and (e) (6)	26.137, 26.167, 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)
Appendix A Subpart C 3.2	26.75 (l) (4), 26.153 (f) (4), and 26.165 (f)
Appendix A Subpart D 4.1	26.153 (d)